UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, *ex rel.* Doris Modglin and Russ Milko, Plaintiffs, vs. DJO GLOBAL INC., DJO LLC, DJO FINANCE LLC, ORTHOFIX, INC., BIOMET, INC. and EBI, LP, Defendants.	CASE NO. CV 12-07152 MMM (JCGx) ORDER GRANTING DEFENDANTS' MOTION TO DISMISS THE CORRECTED THIRD AMENDED COMPLAINT

Qui tam relators Doris Modglin and Russ Milko filed this action against defendants DJO Global Inc. ("DJO Global"), DJO, LLC ("DJO"), DJO Finance LLC ("DJO Finance"), Orthofix, Inc. ("Orthofix"), Biomet, Inc. ("Biomet"), and EBI, LP ("EBI") under seal and *in camera* on August 20, 2012. Relators invoked the court's federal question jurisdiction under 28 U.S.C. § 1331, and alleged a single claim for violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729(a)(1)(A), (B).[1] On December 26, 2012, they filed a first amended complaint, realleging the federal FCA claim and alleging state FCA claims under the equivalent statutes of twenty-nine states: California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island,

[1]Complaint, Docket No. 1 (Aug. 20, 2012).

Tennessee, Texas, Virginia, and Wisconsin.[2] On May 17, 2013, the United States declined to intervene in the case.[3] On July 19, 2013, each of the twenty-nine states declined to intervene.[4] The court unsealed the amended complaint that day.[5]

On October 3, 2013, pursuant to a request by relators, the court dismissed Orthofix.[6] On November 8, 2013, relators filed a second amended complaint, restating their federal and state FCA claims and adding EBI, LLC (with EBI, LP, "EBI") as a defendant.[7] On January 22, 2014, the parties stipulated to dismiss DJO Global and DJO Finance as defendants;[8] the court entered an order on the stipulation on January 28, 2014.[9] On February 20, 2014, the court granted defendants' motion to stay discovery[10] until it decided their pending motion to dismiss the second amended complaint.[11] On May 5, 2014, the court held a hearing on the motion to dismiss the second amended complaint. Following that hearing, the court took the motion under submission and directed the parties to file supplemental briefs addressing four questions.[12] After the parties did so on July 7, 2014,[13] the court

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[2]First Amended Complaint, Docket No. 8 (Dec. 26, 2012).

[3]The United States' Election to Decline Intervention, Docket No. 9 (May 17, 2012).

[4]United States' Election to Decline Intervention, Docket No. 13 (July 19, 2013).

[5]Docket (July 19, 2013).

[6]Request to Dismiss Defendant Orthofix, Inc., Docket No. 18 (Oct. 2, 2013); Order Dismissing Action Against Defendant Orthofix Without Prejudice, Docket No. 19 (Oct. 3, 2013).

[7]Second Amended Complaint ("SAC"), Docket No. 43 (Nov. 8, 2013).

[8]Stipulation to Dismiss Defendants DJO Finance and DJO Global, Docket No. 49 (Jan. 22, 2014).

[9]Order Dismissing Defendants DJO Global and DJO Finance, Docket No. 50 (Jan. 28, 2014).

[10]Order Granting Defendants' Motion to Stay Discovery, Docket No. 57 (Feb. 20, 2014).

[11]Motion to Dismiss Second Amended Complaint, Docket No. 46 (Jan. 20, 2014).

[12]Order Directing Parties to File Supplemental Briefing, Docket No. 67 (June 20, 2014).

[13]Relators' Responses to the Questions Presented in the Court's June 20, 2014 Order, Docket No. 71 (July 7, 2014); Defendants' Joint Supplemental Brief in Support of Motion to Dismiss Second Amended Complaint, Docket No. 72 (July 7, 2014).

issued an order dismissing the second amended complaint on September 2, 2014.[14] The court dismissed the federal Medicare FCA claim based on submission of false claims and false certifications with prejudice except to the extent it was premised on the theory that defendants made implied false certifications by unlawfully promoting their devices for off-label uses.[15] The court dismissed the federal FCA claim without prejudice to the extent based on allegedly false claims submitted to Medicaid, the Federal Employees Health Benefit Program, the Federal Workers Compensation Programs, the Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA"), and/or Tricare.[16] Finally, the court declined to exercise supplemental jurisdiction over relators' state law claims.[17]

On September 22, 2014, relators filed a third amended complaint; subsequently, on September 29, 2014, they filed a corrected third amended complaint.[18] On October 7, 2014, the court entered an order setting a briefing schedule and hearing date for defendants' motions to dismiss the corrected third amended complaint.[19] That motion was filed jointly by defendants on October 22, 2014.[20] Relators oppose the motion.[21]

I. FACTUAL BACKGROUND

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[14]Order Granting Defendants' Motion to Dismiss the Second Amended Complaint ("Order"), Docket No. 74 (Sept. 2, 2014).

[15]*Id*. at 66-67.

[16]*Id*. at 67.

[17]*Id.* at 68.

[18]Third Amended Complaint, Docket No. 75 (Sept. 22, 2014); Corrected Third Amended Complaint ("TAC"), Docket No. 78 (Sept. 29, 2014). All citations or references to the third amended complaint refer to the corrected third amended complaint.

[19]Order Setting Briefing Schedule, Docket No. 80 (Oct. 7, 2014).

[20]Joint Motion to Dismiss Corrected Third Amended Complaint ("Motion"), Docket No. 81 (Oct. 22, 2014).

[21]Opposition to Joint Motion to Dismiss Corrected Third Amended Complaint ("Opposition"), Docket No. 86 (Nov. 24, 2014).

Relators assert that defendants – manufacturers and distributors of durable medical equipment ("DME") – fraudulently caused the government to disburse money by filing claims with Medicare and other federal healthcare plans[22] for reimbursement related to their provision of non-invasive, bone-growth stimulators ("stimulators") that they knew had been prescribed by physicians for an off-label purpose, i.e., one not specifically approved by the Food and Drug Administration ("the FDA"). Defendants allegedly failed to reveal to Medicare and other federal healthcare plans that the stimulators were going to be used for off-label purposes. As the court explained in its order dismissing the second amended complaint, before one can understand the allegations in the complaint, it is necessary to provide an overview of the statutory and regulatory scheme that governs both FDA approval of medical devices and the coverage of such devices by Medicare and other federal programs. The court begins by describing FDA approval of medical devices.

A. Background Regarding FDA Approval of Medical Devices

One of the "core objectives" of the Food, Drug, and Cosmetic Act ("the FDCA"), 21 U.S.C. § 301 *et seq.*, is to ensure that "there is reasonable assurance of the safety and effectiveness of devices intended for human use." *Food and Drug Administration v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133-34 (2000) (citing 21 U.S.C. § 393(b)(2)). To that end, the FDCA classifies medical devices in three categories: Classes I, II, and III. 21 U.S.C. § 360c(a). Class III devices include those that present a potentially unreasonable risk of illness or injury. *Id.*, § 360c(a)(1)(C). Because of the risk associated with such devices, the FDA has determined that the manufacturers of such devices must submit premarket approval ("PMA") applications to the FDA and obtain premarket clearance before offering the devices for sale.[23] 42 C.F.R. § 405.201(b). Class III devices that do not have PMA

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[22]These other plans are Medicaid, the Federal Employees Health Benefit Program, the Federal Worker's Compensation Programs, CHAMPVA, and Tricare.

[23]All manufacturers that wish to market Class III devices must submit a PMA supplement prior to marketing unless the FDA clears a Form 510(k) in which the manufacturer successfully argues that the device should be reclassified as a Class I or II device "because it is substantially equivalent to an existing device so categorized." *United States v. Universal Management Services, Inc.*, 191 F.3d 750, 754 (6th Cir. 1999). Manufacturers that wish to market Class I or II devices must also, except in rare circumstances, submit a Form 510(k) to the FDA in order lawfully to market the device. (Defendants' Request for Judicial Notice in Support of Supplemental Brief ("Defendants' Prior Supp. RJN"), Docket

approval cannot be marketed and are considered "adulterated." 21 U.S.C. § 351(f)(1)(B) ("A . . . device shall be deemed to be adulterated . . . if it is a class III device . . . which . . . is required to have in effect an approved application for premarket approval . . . and . . . which has an application which has been suspended or is otherwise not in effect"); 42 C.F.R. § 405.201(b).

The FDA gives a device PMA approval if it determines that the PMA application contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use. 21 C.F.R. § 814.2(a). It is "a 'rigorous' process in which the manufacturer submits extensive study reports, design specifications and descriptions, samples of the device, and proposed labeling to the FDA, and the FDA conducts a comprehensive review and evaluation of all the submitted documents and materials[.]" *Kashani-Matts v. Medtronic, Inc.*, No. SACV 13–01161–CJC (RNBx), 2013 WL 6147032, *1 (C.D. Cal. Nov. 22, 2013).

If a medical device is used for a purpose other than that for which it has obtained PMA approval, the usage is "off-label." *Carson v. Depuy Spine, Inc.*, 365 Fed. Appx. 812, 815 (9th Cir. Feb. 16, 2010) (Unpub. Disp.) ("Drugs and medical devices are approved or cleared by the FDA for marketing with labels describing the uses and the patient conditions which have been reviewed in the approval or clearance process. Any use by a physician which differs from the use described in the label or from the patient conditions described in the label is called 'off–label'"). The FDCA explicitly protects physicians' ability to prescribe devices for off-label use. 21 U.S.C. § 396 ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship"); see also *Houston v. Medtronic, Inc.*, No. 2:13–cv–01679–SVW (SHx), 2014 WL 1364455, *1 n. 1 ("Physicians are permitted to use Class III devices in off-label manners"). Indeed, off-label use of medical devices is "generally accepted" within the medical community, and § 396 of the FDCA "expressly disclaims any intent to directly regulate the

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No. 73 (July 7, 2014), Exh. 10 at 447 (Medical Devices: Premarket Notification (510k).)

The court took judicial notice of various documents cited in this section in its prior order granting defendants' motion to dismiss the second amended complaint. (Order at 20-29.) The court takes judicial notice of the same documents again to provide adequate background for understanding of the parties' dispute. Citations are to the parties' prior requests for judicial notice.

practice of medicine." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 351 & n. 5 (2001) (citing Beck & Azari, FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions, 53 FOOD & DRUG L.J. 71, 72 (1998) ("Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize")); see also *Kashani-Matts*, 2013 WL 6147032 at *1 n. 4 ("The FDA does not prohibit or regulate off-label use of medical devices by medical professionals, and the Supreme Court has emphasized that off-label use is not merely legitimate but important in the practice of medicine," citing *Buckman Co.*, 531 U.S. at 350).

The FDCA does, however, expressly prohibit Class III device manufacturers from marketing a PMA-approved device for an off-label use. 21 U.S.C. § 331 (proscribing, *inter alia*, "[t]he introduction . . . into interstate commerce of any . . . device . . . that is adulterated or misbranded"); 21 C.F.R. § 814.80 (stating that once the FDA has approved a PMA application, the manufacturer of the approved device may not manufacture, package, store, label, distribute, or advertise the device in a manner that is inconsistent with any conditions of approval specified in the PMA approval order for the device). Because off-label usage of medical devices "is an accepted and necessary corollary of the FDA's mission to regulate in th[e] [medical field] without directly interfering with the practice of medicine," however, *Buckman Co.*, 531 U.S. at 349-50, "a manufacturer is not liable [for having violated the FDCA] merely because it sells a device with knowledge that the prescribing doctor intends an off-label use," *Carson*, 365 Fed. Appx. at 815. The manufacturer can only be liable for violating the FDCA if it markets or promotes the device for that purpose. If a device manufacturer wishes to market a device for an off-label purpose, it must submit a PMA supplement for review and approval by the FDA. 21 C.F.R. § 814.39.

B. Facts Alleged in the Corrected ThirdAmended Complaint Regarding FDA Approval of Defendants' Stimulators

Relators allege that DJO, Biomet, and EBI – a wholly owned subsidiary of Biomet – manufacture and market DME, including stimulators, throughout the United States.[24] They assert that

[24]TAC, ¶¶ 5-6.

the FDA categorizes stimulators as Class III devices, meaning that they must receive PMA approval before they can be marketed.[25] More specifically, they allege that DJO manufactures and markets a stimulator called the SpinaLogic,[26] and that the FDA has approved the SpinaLogic as an adjunct electrical treatment to primary lumbar[27] spinal fusion surgery under PMA Number P910066.[28] Biomet and EBI allegedly manufacture and market a stimulator called the SpinalPak.[29] The FDA has approved the SpinalPak as an adjunct electrical treatment to primary lumbar spinal fusion surgery under PMA Number P850022.[30]

C. Background Regarding Medicare Coverage of Medical Devices

1. Coverage Determinations by Medicare

The Medicare program is a federally funded health insurance program for the aged and disabled created by the Social Security Act ("the Medicare Act"), 42 U.S.C. § 1395, *et seq.* See *International Rehabilitative Sciences Inc. v. Sebelius*, 688 F.3d 994, 997 (9th Cir. 2012) ("Medicare is the federal health insurance program for the elderly and disabled"). Part B of the Medicare Act provides medical insurance for medical and other health services needed by individual plan participants; this includes stimulators and other DME provided to Medicare patients by a DME provider. *Id.* (citing 42 U.S.C. §§ 1395j, 1395k(a)(2), 1395m). Under Part B, "Medicare beneficiaries receive medical treatment and the providers submit claims for government reimbursement." *Id.* (citing § 1395n). Under the Medicare Act,

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[25] *Id.*, ¶ 20.

[26] *Id.*, ¶ 5.

[27] The "lumbar spine" refers to the vertebrae in an individual's lower back. (Merriam-Webster Dictionary, www.merriam-webster.com/dictionary/lumbar (accessed on Apr. 21, 2014) ("relating to or lying near the lower back").)

[28] TAC, ¶ 5.

[29] *Id.*, ¶ 6.

[30] *Id.*

only devices that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" can be reimbursed. 42 U.S.C. § 1395y(a)(1)(A). This limitation on coverage is intended to control Medicare costs. *International Rehabilitative Sciences*, 688 F.3d at 997. The Act states that

> "[a] device is not 'reasonable and necessary' – and thus is not eligible for Medicare coverage – if it is: [(1)] Not 'safe' and 'effective' – that is, if the device has not 'been proven safe and effective based on authoritative evidence' or is not 'generally accepted in the medical community as safe and effective for the condition for which it is used'; [(2)] '[E]xperimental' – that is, 'investigational'; [(3)] Not '[a]ppropriate' for the individual beneficiary's needs; or [(4)] '[S]ubstantially more costly than a medically appropriate and realistically feasible alternative pattern of care.'" *Id.* (citing § 1395y(a)(1)(A) and 54 Fed. Reg. 4302, 4303-04 (Jan. 30, 1989); 60 Fed. Reg. 48417, 48418 (Sept. 19, 1995)).

Cf. Medicare Program Integrity Manual § 13.7.1. (stating that "[i]n order of preference, [local coverage determinations] should be based on: [1] Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and [2] General acceptance by the medical community (standard of practice), as supported by sound medical evidence").[31] "[The Centers for Medicare and Medicaid Services ('CMS')] use[ ] the FDA categorization of a device as a factor in making Medicare coverage decisions." 42 C.F.R. § 405.201(a)(1). Thus, "FDA clearance [ ] is necessary, but not sufficient, for Medicare coverage. . . . To be 'reasonable and necessary' for treatment, a device must be 'safe and effective,' but other considerations are also relevant – like whether there are less costly but equally effective devices available." *International Rehabilitative Sciences*, 688 F.3d at 1002 (emphasis omitted).

In its Medicare Benefit Policy Manual ("the Medicare Manual"), the Department of Health and Human Services ("HHS") considered the FDA categorization of devices and determined generally that

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[31]The court takes judicial notice of the contents of the Medicare Program Integrity Manual. See http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf (accessed on December 31, 2014).

"[d]evices that may be covered under Medicare include the following categories: [1] Devices approved by the FDA through the Pre-Market Approval (PMA) process; [2] Devices cleared by the FDA through the 510(k) process; [3] FDA-approved IDE Category B devices; and [4] Hospital Institutional Review Board (IRB) approved IDE devices."[32]

Within these general categories of devices eligible for coverage, HHS "may make [Medicare] coverage determinations [for certain types of devices] via up-front rules." The agency, however, has "discretion . . . whether to make [broad] determinations [as to whether a particular device is reimbursable] . . . or [whether to have Medicare contractors make that decision based on a] case-by-case adjudication." *Id.* at 1001. When HHS engages in rulemaking regarding the scope of coverage for certain devices, it issues National Coverage Decisions ("NCDs"). "An NCD is a determination . . . of whether a particular item or service is covered nationally under Medicare." 42 C.F.R. § 405.1060(a)(1). NCDs are compiled in the Medicare Manual. "Once published . . . , an NCD is binding on all Medicare carriers."[33] *Almy v. Sebelius*, 679 F.3d 297, 299 (4th Cir. 2012) ("[T]he Secretary [of HHS] can make a 'national coverage determination' (NCD) binding throughout the Medicare system and not subject to review by administrative law judges"); see also 42 C.F.R. § 405.1060(a)(4) ("An NCD is binding on fiscal intermediaries, carriers, . . . [administrative law judges], and the [Medicare Appeals Council]," among others). Additionally, individual carriers – the private insurance carriers with whom HHS contracts to administer claims – can issue Local Coverage Determinations ("LCDs"). LCDs address local coverage issues. *Almy*, 679 F.3d at 299-300. If no NCD or LCD addresses a particular device, contractors determine coverage on a case-by-case basis. *Id.* at 300 ("Finally, if no NCD or LCD is in place, 'contractors may make individual claim determinations,' including whether a particular DME meets the statutory requirement of being 'reasonable and necessary'" (citing 68 Fed. Reg. 63,693)).

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[32]Relators' Request for Judicial Notice in Support of Opposition to Defendants' Motion to Dismiss Second Amended Complaint ("Relators' Prior RJN"), Docket No. 61 (Mar. 19, 2014), Exh. J at 136-137 (Medicare Manual Chapter 14 - Medical Devices).

[33]*Id.*, Exh. H at 94 (Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, § 13.1.1).

The reimbursement of stimulators is covered by NCD 150.2.[34] NCD 150.2 states that stimulators are covered by Medicare for six uses, one of which is "as an adjunct to spinal fusion surgery" for certain patients.[35] There are also four LCDs that address the coverage of stimulators. Each mirrors the criteria set forth in NCD 150.2, in that it provides that stimulators are covered, *inter alia*, "as an adjunct to spinal fusion surgery."[36] Neither NCD 150.2 nor the four LCDs covering stimulators distinguish between stimulators used on one part of the spine, e.g., the cervical spine, versus another, e.g., the lumbar spine. Nor do they distinguish between stimulators based on on-label versus off-label use.[37]

NCD 280.1, the "Durable Medical Equipment Reference List" is a "quick reference tool" that

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[34]Defendants' Request for Judicial Notice in Support of Joint Motion to Dismiss Second Amended Complaint ("Defendants' Prior RJN"), Exh. 1 (National Coverage Determination for Osteogenic Stimulators (150.2) ("NCD 150.2"). The court takes judicial notice of this document, *infra*.

[35]*Id*. at 7.

[36]*Id.*, Exhs. 3 at 15 (Local Coverage Determination (LCD): Osteogenesis Stimulators (LCD L11501), covering Connecticut, D.C., Delaware, Massachusetts, Maryland, Maine, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont ("LCD L11501") ("A spinal electrical osteogenesis stimulator (E0748) is covered only if any of the following criteria are met . . . Following spinal fusion surgery")); Exh. 4 at 33 (Local Coverage Determination (LCD): Osteogenesis Stimulators (LCD L11490), covering Alaska, American Samoa, Arizona, California, Guam, Hawaii, Iowa, Idaho, Kansas, Missouri, Montana, North Dakota, Nebraska, Nevada, Oregon, South Dakota, Utah, Washington, Wyoming, Northern Mariana Islands ("LCD L11490") ("A spinal electrical osteogenesis stimulator (E0748) is covered only if any of the following criteria are met . . . Following spinal fusion surgery")); Exh. 5 at 52 (Local Coverage Determination (LCD): Osteogenesis Stimulators (LCD L5012), covering Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, North Carolina, New Mexico, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, Virginia, Virgin Islands, West Virginia ("LCD L5012") ("A spinal electrical osteogenesis stimulator (E0748) is covered only if any of the following criteria are met . . . Following spinal fusion surgery")); Exh. 6 at 67 (Local Coverage Determination (LCD): Osteogenesis Stimulators (LCD L27026), covering Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, and Wisconsin ("LCD L27026") ("A spinal electrical osteogenesis stimulator (E0748) is covered only if any of the following criteria are met . . . Following spinal fusion surgery")). The court takes judicial notice of these documents *infra*.

[37]See Defendants' Prior RJN, Exhs. 1 (NCD 150.2); 3 (LCD L11501), 4 (LCD L11490), 5 (LCD L5012), and 6 (LCD L27026). The "cervical spine" refers to the vertebrae in an individual's neck. (Merriam-Webster Dictionary, www.merriam-webster.com/dictionary/cervical (accessed on Apr. 21, 2014) ("of or relating to the neck").)

applies "(where appropriate) to all DME national coverage determinations (NCDs)."[38] It provides a list of

> "generic categories of equipment on which NCDs have been made by . . . CMS. . . . In the case of equipment categories that have been determined by CMS to be covered under the DME benefit, the list outlines the conditions of coverage that must be met if payment is to be allowed for the rental or purchase of the DME by a particular patient, or cross-refers to another section of the manual where the applicable coverage criteria are described in more detail. With respect to equipment categories that cannot be covered as DME, the list includes a brief explanation of why the equipment is not covered. . . . When the contractor receives a claim for an item of equipment which does not appear to fall logically into any of the generic categories listed, the contractor has the authority and responsibility for deciding whether those items are covered under the DME benefit. These decisions must be made by each contractor based on the advice of its medical consultants, taking into account: [1] The Medicare Claims Processing Manual, Chapter 20, 'Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)[;] [2] Whether the item has been approved for marketing by the Food and Drug Administration (FDA) and is otherwise generally considered to be safe and effective for the purpose intended; and [3] Whether the item is reasonable and necessary for the individual patient."[39]

NCD 280.1 thus serves as a first point of reference for contractors attempting to determine whether a certain device or a certain use of a device is covered. Specifically, it provides an index of some of the national coverage determinations Medicare has made. It lists some devices that are covered and refers the reader to the NCD controlling that device. It also lists some devices that are not covered and articulates why HHS has determined that that device cannot be covered. For devices that HHS has not

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[38]Relators' Prior RJN, Exh. F (Medicare Manual, Chapter 1, Part 4, Coverage Determinations, § 280.1 – Durable Medical Equipment Reference List ("NCD 280.1")).

[39]*Id.*

explicitly declared covered or uncovered, NCD 280.1 sets forth the factors a contractor must consider in making a case-by-case coverage determination. NCD 280.1 is not comprehensive, however. Certain devices that are covered by a particular NCD are not referenced in NCD 280.1. This is because NCD 280.1 was meant only to aid in determining coverage for "certain pieces of DME and especially for those items commonly referred to by both brand and generic names."[40] As the NCDs are binding on Medicare contractors, the contractors must follow an NCD dictating coverage for a certain device, even if that device is not listed in NCD 280.1.

[40] *Id.*

2. The Reimbursement Process

To submit a claim for reimbursement, DME providers fill out and submit to Medicare CMS Form 1500.[41] Section 23 of the form includes a space for the provider to list any PMA approval number covering the device for which it seeks reimbursement.[42] Providers seeking reimbursement for stimulators must also include a "KF" modifier on CMS Form 1500, which indicates that the provider is billing Medicare for a Class III device.[43]

Together with CMS Form 1500, the provider must submit a Certificate of Medical Necessity.[44] The Certificate of Medical Necessity used for Class III stimulators is CMS 847.[45] CMS 847 has four sections. Section A seeks general information concerning the patient, physician, and supplier.[46] Section B requests information regarding the medical necessity for the device, and states: "Information in this Section May Not Be Completed by the Supplier of the Items/Supplies." Section C provides space for a "Narrative Description of Equipment and Cost."[47] Section C instructs the person completing the form to provide a "(1) Narrative description of all items, accessories and options ordered; (2) [the] Supplier's charge; and (3) [the] Medicare Fee Schedule Allowance for each item, accessory, and option."[48] Section

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[41]Relators' Prior RJN, Exh. R (Health Insurance Claims Form 1500 ("CMS Form 1500")). The court takes judicial notice of this document *infra*.

[42]*Id.*

[43]CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 236, at 3, http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R236CP.pdf (accessed on April 24, 2014) ("Modifier KF is a pricing modifier. The description for modifier KF is as follows: Item designated by FDA as class III device"). The court takes judicial notice of this fact based on an official document available on the CMS website.

[44]Defendants' Prior RJN, Exh. 2 at 11 (Certificate of Medical Necessity CMS-847 - Osteogenesis Stimulators ("CMS 847")).

[45]*Id.*

[46]*Id.*

[47]*Id.*

[48]*Id.*

D is the physician's attestation and signature.[49]

The DME provider must also include a Healthcare Common Procedure Coding System ("HCPCS") number for the device for which it is requesting reimbursement on both CMS Form 1500 and CMS 847.[50] There is a generic HCPCS code number for all stimulators: E0748.[51]

By regulation, DME providers seeking reimbursement must furnish sufficient information to Medicare's claim processing contractors that they can determine whether payment is due. 42 C.F.R. § 424.5(a)(6) ("As a basis for Medicare payment, the following conditions must be met: . . . The provider, supplier, or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment").

D. Facts Alleged in the Second Amended Complaint Regarding Defendants' Submission of Claims to the Medicare Program

Relators allege that defendants are approved Medicare DME providers.[52] They assert that when a physician prescribes a stimulator manufactured by one of the defendants, a local distributor under contract to the defendant collects relevant medical records and prescriptions and forwards them to an insurance administrator at the defendant's home office.[53] The insurance administrator and claims processor then prepare and submit claims to Medicare and other insurance carriers.[54] Relators assert that since approximately September 18, 2001, defendants have routinely submitted false or fraudulent claims for stimulators to Medicare. Specifically, they allege that defendants have requested reimbursement for stimulators approved for lumbar spine use when they knew, and did not reveal, that the stimulators had

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[49]*Id.*

[50]Relators' Prior RJN, Exh. R (CMS Form 1500); Defendants' RJN, Exh. 2 (CMS 847).

[51]Defendants' Prior RJN, Exhs. 3 (LCD L11501), 4 (LCD L11490), 5 (LCD L5012), and 6 (LCD L27026).

[52]TAC, ¶¶ 5-6.

[53]*Id.*, ¶ 111.

[54]*Id.*

been distributed for off-label cervical spinal use.[55] Relators contend that the stimulators are not reimbursable if they are not distributed for the use for which they have PMA approval.[56] They allege that, by indicating on CMS Form 1500 a PMA approval number for a stimulator approved only for lumbar, and not for cervical, spine use, defendants expressly or implicitly misrepresent the device's intended use. Stated differently, they contend that by reporting their stimulator's PMA approval number on CMS Form 1500, defendants affirmatively represent that the stimulator will be used on the lumbar spine when they know it will be used on the cervical spine instead.[57] Relators assert that, because there is only one HCPCS code covering stimulators used on all parts of the spine, and because defendants' stimulators are only approved for use on the lumbar spine, unless defendants specifically indicate in the narrative description portion of CMS 847 that the device has been distributed for an off-label use, they violate the requirement that they furnish sufficient information to permit Medicare's claim processing contractors to determine whether payment is due. Relators also contend that by failing to indicate in the narrative description portion of CMS 847 that the stimulator is being distributed for an off-label use, defendants expressly and/or impliedly misrepresent that the stimulator is being distributed and used for the use that is PMA-approved and use of the device is therefore reimbursable.[58]

As proof that defendants have submitted such claims for reimbursement, relators plead facts concerning their interactions with defendants over the years. They allege that in 1997, relator Milko was hired as a direct sales representative for Orthofix to promote and sell stimulators.[59] Orthofix is a major manufacturer and distributor of stimulators and defendants' primary competitor.[60] Orthofix manufactures and distributes the only stimulator with PMA approval for cervical use: the Cervical-

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[55] *Id.*

[56] *Id.*

[57] *Id.*, ¶ 115.

[58] *Id.*, ¶ 114.

[59] *Id.*, ¶ 126.

[60] *Id.*, ¶ 58.

Stim.[61] Orthofix developed the Cervical-Stim after the FDA issued a public warning in 1997 stating that Orthofix had been unlawfully marketing its Physio-Stim stimulator for cervical use because it did not have PMA approval to use the device in that manner. Orthofix's PMA approval for the Physio-Stim covers only use for "the treatment of nonunion of long bone fractures acquired secondary to trauma and for the treatment of flat bones, excluding vertebra."[62] The warning letter stated that use of the Physio-Stim for treatment of cervical spine fusion was "a change in indication that required a PMA [s]upplement" if Orthofix intended to continue marketing the device for that purpose.[63]

Relators allege that on July 1, 2005, Milko became an Orthofix distributor and that he has continued in that capacity since, marketing and selling the Cervical-Stim and Orthofix's other, non-cervical stimulators.[64] They assert that because of his position with Orthofix, Milko learned that defendants were distributing their stimulators for off-label, cervical use.[65] Specifically, they allege that Milko heard that DJO sales personnel verbally instructed patients to use the SpinaLogic by folding it up, placing a pillow over it, and lying their head on the pillow for 30 minutes and that they reassured doubtful patients that the device worked better on the cervical spine than on the lumbar spine, although not approved for that use, because the cervical spine was a smaller area to heal.[66]

In April 2011, a sales associate working for Milko left his employ and went to work for DJO; the associate sold the SpinaLogic in the same geographic area in which Milko sold Orthofix products. Milko allegedly lost "some of his best physician referral sources, including physicians who regularly referred Medicare patients for cervical bone growth stimulators, even though [as noted,] Orthofix sold

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[61] *Id.*, ¶ 61.

[62] *Id.*, ¶ 60.

[63] *Id.*

[64] *Id.*, ¶ 126.

[65] *Id.*, ¶ 127.

[66] *Id.*

the only approved cervical device."[67] As a result, Milko concluded that DJO must have filled cervical stimulator prescriptions for his former physician clients with the SpinaLogic and charged Medicare and other federally sponsored health care programs for it.[68]

Relators assert that Milko sued his former associate for violating a non-competition agreement.[69] During the lawsuit, Milko deposed two referring physicians, both of whom are Medicare providers who perform lumbar and cervical spine fusion surgeries. Both doctors testified that they had ordered stimulators from Milko's former associate.[70]

Relators allege that on June 21, August 30, and September 1, 2011, the Spine and Brain Institute in Las Vegas, Nevada, faxed prescriptions on behalf of Dr. John Anson, the ordering physician, to the local DJO sales representative for SpinaLogic; the institute indicated that the patients were Medicare beneficiaries and were diabetic.[71] On February 2, 2012, DJO submitted a claim to the Minnesota Health Care Programs for a stimulator to be used following cervical fusion surgery. The Minnesota program paid DJO $835.82.[72]

In August 2012, DJO's Regional Sales Director and a DJO sales representative told relator Modglin, a private investigator licensed by the state of California, that DJO routinely billed federally sponsored health care programs like Medicare and Medicaid for off-label distribution of SpinaLogic for use on the cervical spine.[73] In March 2013, Milko attended the national convention of the American

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[67] *Id.*, ¶ 128.

[68] *Id.*

[69] *Id.*

[70] *Id.*, ¶ 129. Relators allege these physicians testified that they did not complete CMS 847 forms in connection with these orders. (*Id.*) They do not plead, however, that defendants forged the physicians' signatures on the form, that defendants wrongfully completed Section B, or that when a manufacturer completes the form instead of the physician, this alone means the manufacturer has made a false claim to the government by submitting the form.

[71] *Id.*, ¶ 45.

[72] *Id.*

[73] *Id.*, ¶¶ 3, 135.

Academy of Orthopedic Surgeons in Chicago. There, he spoke with DJO representatives, who told him that in some areas of the country, at least 75% of DJO's business came from selling the SpinaLogic for cervical use.[74] Relators assert that at some point, two patients told Milko when he fitted them with lumbar stimulators that they had previously been fitted with the SpinaLogic following prior, cervical spinal surgeries.[75]

In May 2013, an Orthofix sales representative in Temecula, California, switched companies and began to sell the SpinaLogic. After two weeks, the representative returned to Orthofix. Relators contend that while working for DJO, DJO upper management told the sales representative that 40% of the company's SpinaLogic business involved off-label, cervical spine applications.[76]

As respects the SpinalPak manufactured by Biomet and EBI, relators allege that Milko has provided replacement Cervical-Stims to Medicare patients who complained that their use of the SpinalPak on the cervical spine caused skin irritation on their necks.[77] Relators assert that Milko confirmed these complaints by observing large, red skin irritations on the patients.[78] The patients purportedly said that Biomet and EBI representatives told them to use the SpinalPak only for a couple of hours per day, as tolerated.[79]

On February 16 and March 10, 2010, and again on March 18, 2011, Biomet and EBI submitted claims to the Minnesota Health Care Programs for off-label stimulators under Code E0748, for use following cervical spinal fusion surgery. They were paid $817.05, $3,901.41, and $3,897.50 on the claims, respectively.[80]

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[74] *Id.*, ¶ 130.

[75] *Id.*, ¶ 133.

[76] *Id.*, ¶ 130.

[77] *Id.*, ¶ 141.

[78] *Id.*

[79] *Id.*

[80] *Id.*, ¶ 146.

Relators allege that on September 5, 2012, Dr. David Ketroser, a neurologist, contacted the office of a neurosurgeon in Minnesota. An employee confirmed that the office routinely prescribed the SpinalPak for cervical and lumbar fusions, for both Medicare and non-Medicare patients, and that it had done so for a particular patient Ketroser had referred.[81]

On May 20, 2013, Milko asked a former Biomet distributor who now sells Orthofix devices how Biomet succeeded in securing Medicare payment for a lumbar-only device when the physician's order indicated cervical application. The individual purportedly told him that neither the CMS 847 Form nor the E0748 billing code reveal the level of the spine for which the device was ordered.[82] On May 29, 2013, a former Biomet sales representative told Modglin that she had sold Biomet's devices off-label to Medicare patients for use on the cervical spine.[83] On May 31, 2013, a former Biomet sales representative told Modglin that he had sold the SpinalPak to Medicare and Medicaid patients in Texas between 2009 and 2011 for use on the cervical spine.[84]

E. Defendants' Request for Judicial Notice

Defendants request that the court take judicial notice of certain documents they contend are relevant to this motion.[85] All of the applications are unopposed. In deciding a Rule 12(b)(6) motion, the court generally looks only to the face of the complaint and documents attached thereto. *Van Buskirk v. Cable News Network, Inc.*, 284 F.3d 977, 980 (9th Cir. 2002); *Hal Roach Studios, Inc. v. Richard Feiner & Co., Inc.*, 896 F.2d 1542, 1555 n. 19 (9th Cir. 1990). A court normally must convert a Rule 12(b)(6) motion into a Rule 56 motion for summary judgment if it "considers evidence outside the pleadings. . . . A court may, however, consider certain materials – documents attached to the complaint, documents incorporated by reference in the complaint, or matters of judicial notice – without converting the motion. . . ." *United States v. Ritchie*, 342 F.3d 903, 907-08

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[81] *Id.*, ¶ 144.

[82] *Id.*, ¶ 142.

[83] *Id.*, ¶ 145.

[84] *Id.*, ¶ 146.

[85] Defendants' Request for Judicial Notice ("RJN"), Docket No. 82 (Oct. 22, 2014).

(9th Cir. 2003). See *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) (a court may consider "other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice"); *Branch v. Tunnell* 14 F.3d 449, 453 (9th Cir. 1994) (noting that a court may consider a document whose contents are alleged in a complaint, so long as no party disputes its authenticity), overruled on other grounds in *Galbraith v. County of Santa Clara*, 307 F.3d 1119 (9th Cir. 2002). Under Rule 201, the court may judicially notice a fact that is "not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." FED.R.EVID. 201(b).

Defendants ask the court to take judicial notice of three exhibits. The first contains excerpts of the October 1, 2011 Michigan Medicaid Provider Manual. The second contains excerpts of the October 1, 2005 Michigan Medicaid Provider Manual, while the third contains excerpts of the Nevada Medicaid Services Manual.[86] Each of the exhibits is found on the state's medicare websites. Under Rule 201, the court can take judicial notice of "[p]ublic records and government documents available from reliable sources on the Internet," such as websites run by governmental agencies. See *Hansen Beverage Co. v. Innovation Ventures, LLC*, No. 08–CV–1166–IEG, 2009 WL 6597891, *1 (S.D. Cal. Dec. 23, 2009) (citing *Jackson v. City of Columbus*, 194 F.3d 737, 745 (6th Cir. 1999)). See also *Daniels-Hall v. National Education Association,* 620 F.3d 992, 999 (9th Cir. 2010) (taking judicial notice of information on the websites of two school districts because they were government entities); *Paralyzed Veterans of Am. v. McPherson*, No. C 06–4670, 2008 WL 4183981, *5 (N.D. Cal. Sept. 8, 2008) ("Information on government agency websites has often been treated as properly subject to judicial notice"). The court therefore grants defendants' request for judicial notice.

II. DISCUSSION

[86]RJN, Exhs 1-3.

A. Legal Standard Governing Motions to Dismiss

A Rule 12(b)(6) motion tests the legal sufficiency of the claims asserted in the complaint. A Rule 12(b)(6) dismissal is proper only where there is either a "lack of a cognizable legal theory," or "the absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dept.*, 901 F.2d 696, 699 (9th Cir. 1988). The court must accept all factual allegations pleaded in the complaint as true, and construe them and draw all reasonable inferences from them in favor of the nonmoving party. *Cahill v. Liberty Mut. Ins. Co.*, 80 F.3d 336, 337-38 (9th Cir. 1996); *Mier v. Owens*, 57 F.3d 747, 750 (9th Cir. 1995).

The court need not, however, accept as true unreasonable inferences or conclusory legal allegations cast in the form of factual allegations.[87] See *Bell Atlantic Corp. v. Twombly*, 540 U.S. 544, 553–56 (2007) ("While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do"). Thus, a plaintiff's complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' . . . A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); see also *Twombly*, 550 U.S. at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)" (citations omitted)); *Moss v. United States Secret Service*, 572 F.3d 962, 969 (9th Cir. 2009) ("[F]or a complaint to survive a motion to dismiss, the non-conclusory 'factual content,' and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief," citing *Iqbal* and *Twombly*).

B. Relators' Federal FCA Claim

Because relators' FCA claim provides the only basis for subject matter jurisdiction, the court

[87]For this reason, although the complaint contains many allegations concerning the applicable law, the court does not accept them as true.

addresses it first.

1. Legal Standard Governing Federal FCA Claims

The FCA, 31 U.S.C. §§ 3729 *et seq*., provides for "the recovery of civil penalties from those who knowingly present a false or fraudulent claim to the federal government for payment, or knowingly use a false record to avoid or decrease an obligation to pay the federal government." *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1467 n. 1 (9th Cir.), cert. denied, 519 U.S. 865 (1996). Originally enacted to punish and prevent massive frauds perpetrated by large contractors during the Civil War, the FCA's chief goal was to provide for restitution to the government of money taken from it by fraud. See *United States v. Bornstein*, 423 U.S. 303, 309 (1976). The Supreme Court has refused to adopt a restrictive reading of the statute, however, holding that the FCA is a "remedial statute [that] reaches beyond 'claims' which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money." *United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968); *United States v. McLeod*, 721 F.2d 282, 284-85 (9th Cir. 1983).

The FCA authorizes individuals, known as "relators," to file civil suits, known as "qui tam actions," against persons who present false claims to the government.[88] 31 U.S.C. § 3730. It makes liable any person who has (1) knowingly presented or caused to be presented a false or fraudulent claim; (2) knowingly made, used or caused to be made or used a false record or statement to get a false or fraudulent claim paid; or (3) conspired to defraud the government by getting a false or fraudulent claim paid. 31 U.S.C. § 3729(a)(1)-(3). The FCA defines "knowing" as having actual knowledge of

[88]An FCA action can be commenced in one of two ways. The government can file a civil action against the alleged false claimant. 31 U.S.C § 3730(a). Alternatively, a private person, a relator, can commence a qui tam civil action against the alleged false claimant "for the person and for the United States Government . . . in the name of the Government." 31 U.S.C. § 3730(b)(1). When a private person files a false claims action, the government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and material evidence and information supporting the complaint. 31 U.S.C. § 3730(b)(2). If the government declines to assume responsibility for the action, the relator has the right to conduct the action in the government's name. 31 U.S.C. § 3730(b)(4)(B). If the government elects to prosecute the action, the relator will receive 15 to 25 percent of any recovery, depending on the extent to which he substantially contributes to prosecution of the action. 31 U.S.C. § 3730(d)(1). If the government chooses not to intervene, the relator will receive 25 percent to 30 percent of any recovery. 31 U.S.C. § 3730(d)(2).

information, or acting in either deliberate ignorance or reckless disregard of the information's truth or falsity. 31 U.S.C. § 3729(b). Congress amended the FCA to include this definition to make "'firm . . . its intention that the act not punish honest mistakes or incorrect claims submitted through mere negligence.'" *United States ex rel. Hochman v. Nackman*, 145 F.3d 1069, 1073 (9th Cir. 1998) (quoting S.Rep. No. 99-345 at 7 (1986)); see also *United States ex rel. Hagood* v. *Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991) ("[T]he statutory definition of 'knowingly' requires at least 'deliberate ignorance' or 'reckless disregard'"). Thus, "[t]he phrase 'known to be false' . . . means [known to be] 'a lie.'" *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992); see *United States ex rel. Anderson v. Northern Telecom, Inc.*, 52 F.3d 810, 815-16 (9th Cir. 1995). "The FCA does not define false. Rather, courts decide whether a claim is false or fraudulent by determining whether a defendant's representations are accurate in light of applicable law." *United States v. Bourseau*, 531 F.3d 1159, 1170-71 (9th Cir. 2008).

"A civil action for False Claims Act liability requires four essential elements: '(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due.'" *United States ex rel. Ruhe v. Masimo Corp.*, 977 F.Supp.2d 981, 991 (C.D. Cal. 2013) (citing *United States ex rel. Hendow v. University of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006)); see also *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 997 (9th Cir. 2010) (same). A plaintiff "must show an actual false claim for payment being made to the Government"; "[e]vidence of an actual false claim is the *sine qua non* of a False Claims Act violation." *United States ex rel. Aflatooni v. Kitsap Physicians Serv.*, 314 F.3d 995, 1002 (9th Cir. 2002); see also *Cafasso, United States ex rel. v. General Dynamics C4 Systems, Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) ("'It seems to be a fairly obvious notion that False Claims Act suit ought to require a false claim.' '[T]he [FCA] attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the "claim for payment,"'" citing *Aflatooni*, 314 F.3d at 997, and *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995) (internal alterations original)); *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266-67 (9th Cir. 1996) ("Violations of laws, rules, or regulations alone do not create a cause of action under the FCA. It is the false *certification* of compliance which creates liability when certification is a prerequisite to obtaining a government benefit. . . . [Thus there is no FCA

liability] where regulatory compliance was not a *sine qua non* of receipt of state funding").

Relators who assert that a defendant has made a false claim can allege that defendant has submitted a factually false claim, or that defendant has given a false certification. The prototypical false claims action alleges a factually false claim, i.e., an explicit lie in a claim for payment, such as an overstatement of the amount due. See *Maa v. Ostroff*, No. 12–cv–00200–JCS, 2013 WL 1703377, *15 n. 3 (N.D. Cal. Apr. 19, 2013) ("The 'factually false' theory refers to the 'archetypal *qui tam* False Claims Action' in which 'a private company overcharges under a government contract, [and] the claim for payment itself is literally false or fraudulent,'" citing *Hendow*, 461 F.3d at 1170 (alteration original)). Relators relying on a false certification theory allege that defendant's claim is false because defendant certified to a government agency that it had complied with laws, rules, or regulations governing the reimbursement of claims or other provision of benefits when it had not. See *Hopper*, 91 F.3d at 1266 ("Violations of laws, rules, or regulations alone do not create a cause of action under the FCA. It is the false *certification* of compliance [with those rules] which creates liability when certification is a prerequisite to obtaining a government benefit"). There are two types of false certification claims – expressly false certification and impliedly false certification.

> "Express certification simply means that the entity seeking payment certifies compliance with a law, rule or regulation as part of the process through which the claim for payment is submitted. Implied false certification occurs when an entity has previously undertaken to expressly comply with a law, rule, or regulation, and that obligation is implicated by submitting a claim for payment even though a certification of compliance is not required in the process of submitting the claim." *Ebeid*, 616 F.3d at 998.

To show that claims were false under a false certification theory, a complaint "must plead with particularity allegations that provide a reasonable basis to infer that (1) the defendant explicitly undertook to comply with a law, rule or regulations that is implicated in submitting a claim for payment and that (2) claims were submitted (3) even though the defendant was not in compliance with that law, rule or regulation." *Id.*

Like other allegations of fraud in federal court, claims "brought under the FCA must fulfill the requirements of Rule 9(b)" of the Federal Rules of Civil Procedure. *United States ex rel. Lee v.*

SmithKline Beecham, Inc., 245 F.3d 1048, 1051 (9th Cir. 2001); see also *Cafasso*, 637 F.3d at 1054 ("The heightened pleading standard of Rule 9(b) governs FCA claims"). Under Rule 9(b), "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." FED.R.CIV.PROC. 9(b). Conclusory allegations are insufficient, and the facts constituting the fraud must be alleged with specificity. *Moore v. Kayport Package Exp., Inc.*, 885 F.2d 531, 540 (9th Cir. 1989). "A pleading is sufficient under Rule 9(b) if it identifies the circumstances constituting fraud so that a defendant can prepare an adequate answer to the allegations. While statements of the time, place and nature of the alleged fraudulent activities are sufficient, mere conclusory allegations of fraud are insufficient." *Id.* at 540 (citation omitted). See also *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997) (to satisfy Rule 9(b), "the complaint [must] identif[y] the circumstances of the alleged fraud so that defendants can prepare an adequate answer" (internal quotations omitted)); *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990) ("Although states of mind may be pleaded generally, the 'circumstances' must be pleaded in detail. This means the who, what, when, where, and how"); *Walling v. Beverly Enters.*, 476 F.2d 393, 397 (9th Cir. 1973) (concluding that allegations stating the time, place, and nature of allegedly fraudulent activities met Rule 9(b)'s particularity requirement).

Thus, to satisfy Rule 9(b), a plaintiff must specify the content of the fraudulent representation, the person who made it, when and where the representation was made, and the manner in which it was untrue and misleading, or the circumstances indicating that it was false. See *In re GlenFed Securities Litigation*, 42 F.3d 1541, 1548 (9th Cir. 1994) (en banc). See also *Vess v. Ciba-Geigy Corp.*, 317 F.3d 1097, 1107 (9th Cir. 2003) (plaintiff "alleges that the APA misrepresented its connection to Novartis, but he does not identify any specific misrepresentations or specify when and where they occurred. These allegations are not particular enough to satisfy Rule 9(b)").

"The knowledge or scienter element of a fraud claim need not be pleaded with particularity, but may be [ ] alleged generally pursuant to Rule 9(b). However, knowledge must still be pleaded sufficiently to make entitlement to relief plausible." *Owens v. Bank of America, N.A.*, No. 11–cv–4580–YGR, 2013 WL 1820769, *4 (N.D. Cal. Apr. 30, 2013); see also *Odom v. Microsoft Corp.*, 486 F.3d 541, 554 (9th Cir. 2007) ("While the factual circumstances of the fraud itself must be alleged with particularity, the state of mind – or scienter – of the defendants may be alleged more generally");

In re GlenFed Inc. Securities Litigation, 42 F.3d at 1547 ("We conclude that plaintiffs may aver scienter generally, just as the rule states – that is, simply by saying that scienter existed").

2. FCA Liability Premised on Implied False Certifications

The second amended complaint alleged that Medicare covers defendants' stimulators only when prescribed for on-label use, and that defendants' failure affirmatively to disclose the fact that the stimulators had been prescribed for off-label use constituted the submission of a false claim. Relators also alleged that defendants made an implied false certification because they had an affirmative obligation – under 21 C.F.R. §§ 801.4 and § 814.39 – to seek a PMA supplement given knowledge that the devices were prescribed from time to time for off-label uses. The court disagreed that these allegations were sufficient to plead the submission of a false claim or making of a false certification.

With regard to relators' argument that failure to disclose that the stimulators had been prescribed for off-label use, the court explained that because "the Medicare regulations and the Medicare Manual do not bar reimbursement of devices supplied for off-label use, the fact that defendants have allegedly not filed a PMA supplement or obtained PMA approval for cervical use of their stimulators does not bar them from obtaining reimbursement for the devices if HHS has otherwise determined that they are 'reasonable and necessary.'"[89] See *United States ex rel. Nowak v. Medtronic, Inc.*, 806 F.Supp.2d 310, 348 (D. Mass. 2011) ("Nowak relies almost entirely upon the flawed rationale that because the biliary stents are unapproved for use in the biliary tree, they are 'categorically' or 'statutorily' nonreimbursable under the various federal health care programs"); *United States ex rel. Ruhe v. Masimo Corp.*, 977 F.Supp.2d 981, 993 (C.D. Cal. 2013) ("In the context of False Claims Act cases involving promotion of medical devices, courts have recognized that 'off-label use of a medical device is not the same as a medically unnecessary use of that drug or device'").

The court also found defendants' false certification argument unavailing. It noted that although § 801.4 appears, at first blush, to support relators' theory, courts in the Ninth Circuit and elsewhere have not construed § 801.4 as imposing an affirmative duty on manufacturers to file a PMA supplement under § 814.39 whenever time they know or should know that a patient intends to use, or that a physician has

[89]Order at 45-46.

prescribed or will prescribe, a device for off-label use.[90] The court observed that the Ninth Circuit had unequivocally concluded in *Carson v. Depuy Spine, Inc.*, 365 Fed. Appx. 812, 815 (9th Cir. Feb. 16, 2010) (Unpub. Disp.), that "a manufacturer is not liable [under the FCA] merely because it sells a device with knowledge that the prescribing doctor intends an off-label use." Although not binding, the court found this explicit Ninth Circuit holding highly persuasive, and thus declined to accept relators' theory. The court also discussed *Riley v. Cordis Corp.*, 625 F.Supp.2d 769, 781 (D. Minn. 2009), in which a Minnesota district court directly addressed whether § 801.4 imposed an affirmative duty on manufacturers to file a PMA supplement whenever they know that their products are being used for off-label purposes, and concluded that it did not. The court noted that even without *Carson*, it would find *Riley* persuasive and would adopt its reasoning. As a result, the court found that relators' false certification claim failed. The court therefore dismissed relators' Medicare FCA claim with prejudice to the extent it was premised on these theories.

The court nonetheless concluded that relators might be able to allege an FCA claim under an implied false certification theory based on off-label promotion of the stimulators by defendants. Stated differently, the court noted it was possible that relators could allege that defendants engaged in off-label promotion of the type that would trigger a duty to file PMA supplement, and hence permit them to plead submission of false claims based on an implied false certification theory.[91] Accordingly, the court granted "narrow" leave to amend "limited to this one theory."[92] The initial question, therefore, is whether relators have adequately alleged that defendants engaged in off-label promotion of the stimulators.

a. Whether the Corrected Third Amended Complaint Sufficiently Alleges that Defendants Engaged in Off-Label Promotion

Defendants contend that as alleged in the corrected third amended complaint, relators' assertion that they were required to file a PMA supplement is flawed for two reasons. First, defendants maintain

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[90] *Id.* at 54-55.

[91] *Id.* at 67.

[92] *Id.*

that to the extent relators rely on the false claim and false certification theories they pled in the second amended complaint – allegations the court dismissed with prejudice – the claim once again fails.[93] The court agrees. Relators devote a significant portion of their opposition to discussion of § 814.39, but appear to misunderstand the order dismissing the second amended complaint and granting limited leave to amend the Medicare FCA claim. Relators contend that "nowhere does the [court's prior order] state that the *only* way that an affirmative obligation to comply with PMA [s]upplement requirements can arise is through off-label 'marketing.'"[94] While this may be true, what relators fail to appreciate is that the court granted leave to amend only to the extent they could plead implied false certification due to defendants' off-label promotion of the stimulators and failure to submit a PMA.[95] To the extent relators attempt to replead an FCA Medicare claim based on the fact that defendants submitted claims without affirmatively disclosing that their stimulators would be used for off-label purposes and/or based on the fact that defendants purportedly certified compliance with all applicable rules and regulations falsely because they had not submitted a PMA supplement to cover known off-label prescription or use, therefore, they exceeded the scope of the leave to amend granted. The court therefore dismisses these allegations again with prejudice. See *Raiser v. City of Los Angeles*, No. CV 13-2925 RGK (RZ), 2014 WL 794786, *4 (C.D. Cal. Feb. 26, 2014) ("When a district court grants leave to amend for a specified purpose, it does not thereafter abuse its discretion by dismissing any portions of the amended complaint that were not permitted"); *Haines v. Brand*, No. CV 11-01335 YGR, 2012 WL 2237366, *7 (N.D. Cal. June 14, 2012) ("Judge Chen previously dismissed Plaintiff's claim for intentional infliction of emotional distress with prejudice on the basis that the Brand is immune from this state tort law claim . . . . Therefore, Plaintiff's claim for intentional infliction of emotional distress, which already was

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[93]Motion at 10.

[94]Opposition at 23.

[95]Order at 68 ("Relators' federal FCA claim is dismissed with prejudice to the extent it is based on defendants' submission of claims to Medicare; *the only exception* is a claim alleging that defendants made impliedly false certifications to Medicare that they were in compliance with all applicable regulations when they had an affirmative duty to file a PMA supplement because their employees were promoting use of the stimulators for the cervical spine." (emphasis added)).

dismissed with prejudice, is Dismissed With Prejudice, again."); *Kennedy v. Full Tilt Poker*, No. CV 09–07964 MMM (AGRx), 2010 WL 3984749, *1 (C.D. Cal. Oct.12, 2010) (noting that the court had stricken a third amended complaint because plaintiffs' new claims and the addition of new defendants "exceeded the authorization to amend the court granted," and plaintiffs had not sought leave to add new claims or defendants as required by Rule 15); *PB Farradyne, Inc. v. Peterson*, No. C 05-3447 SI, 2006 WL 2578273, *3 (N.D. Cal. Sept. 6, 2006) (striking, without leave to amend, a new theory of liability alleged in third amended complaint because the new claim was "outside the scope of the leave to amend granted" when court dismissed second amended complaint); *Serpa v. SBC Telecommunications, Inc.*, No. C 03–4223 MHP, 2004 WL 2002444, *3 (N.D. Cal. Sept. 7, 2004) (striking a claim asserted for the first time in an amended complaint, since the new claim exceeded the scope of the court's order granting limited leave to amend); cf. Siskiyou Regional Education Project v. United States Forest Service, 565 F.3d 545, 559–60 (9th Cir. 2009) (affirming a district court's decision to strike intervenor's answer/counterclaims because allegations "exceeded the bounds" of the limited intervention granted).[96]

As respects the only portion of the federal Medicare FCA claim in the corrected third amended complaint that relators were granted leave to plead – i.e., an implied false certification claim premised on off-label promotion and failure to submit a PMA supplement – defendants contend that relators have failed to allege with the requisite specificity under Rule 9(b) that defendants in fact marketed their devices for off-label use.[97] Defendants assert that the corrected third amended complaint does not describe with specificity any instance in which a DJO or EBI sales representative marketed the

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[96]Alternatively, the court could strike the allegations under Rule 12(f). See FED.R.CIV.PROC. 12(f) ("The court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter. The court may act: (1) on its own; or (2) on motion made by a party either before responding to the pleading or, if a response is not allowed, within 21 days after being served with the pleading"); *Barker v. Avila*, No. 2:09-cv-0001-GEB-JFM, 2010 WL 31701067, *1-2 (E.D. Cal. Aug. 11, 2010) (striking an amendment to a federal law claim where the court had granted leave to amend only state law claims); *PB Farradyne, Inc. v. Peterson*, No. CV 05–3447 SI, 2006 WL 2578273, *3 (N.D. Cal. Sept. 6, 2006) (striking allegations exceeding scope of leave to amend).

[97]*Id.* at 11-14.

SpinaLogic or SpinaPak for cervical spine use. Nor, they note, does it identify any sales representatives who engaged in off-label promotion, or any manager or executive who directed or sanctioned off-label promotion. Finally, defendants contend that no allegations suggest when the purported marketing occurred, where it occurred, or under what circumstances it occurred.[98] As noted, to satisfy Rule 9(b), relators must specify the content of the fraudulent representation or omission, the person who made it, when and where the representation or omission was made, and the manner in which it was untrue and misleading, or circumstances indicating that it was false. See *GlenFed Securities Litigation*, 42 F.3d at 1548; *Ebeid*, 616 F.3d at 999 (holding that FCA claims cannot be pled under a "relaxed" Rule 9(b) standard).[99]

Given the theory on which a claim of implied false certification due to off-label promotion and failure to submit a PMA supplement is based, pleading specific facts concerning any off-label promotion by defendants is necessary to provide the "particular details of [the] scheme to submit false claims." *Ebeid*, 616 F.3d at 998-99; see *United States ex rel. Bennett v. Medtronic, Inc.*, 747 F.Supp.2d 745, 779 (S.D. Tex. 2010) ("In addition, the relators have failed to plead with sufficient particularity the alleged false claims. The relators have not identified any Medtronic employees who engaged in off-label promotion nor specific physicians or hospitals who received the promotions. They have not alleged the 'who' or 'where' of the alleged fraud"); cf. *Hawkins v. Medtronic, Inc.*, No. CV 13-00499 AWI SK, 2014 WL 346622, *13 (E.D. Cal. Jan. 30, 2014) ("Plaintiff fails to allege not only the content of the off-

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[98] *Id.* at 12.

[99] In *Ebeid*, the Ninth Circuit rejected the relator's argument that "the traditional pleading standards for fraud under Rule 9(b) should be relaxed [in implied false certification cases] because the alleged fraud was of an extended duration and 'the billing information is solely in Lungwitz's possession.'" *Ebeid*, 616 F.3d at 999. The court held that:

> To be sure, Ebeid is not privy to the details of patient billing. As he points out, in the securities fraud context we have held that 'Rule 9(b) may be relaxed to permit discovery in a limited class of corporate fraud cases where the evidence is within a defendant's exclusive possession.' We are not persuaded that this limited principle should be applied in this case. To jettison the particularity requirement simply because it would facilitate a claim by an outsider is hardly grounds for overriding the general rule, especially because the FCA is geared primarily to encourage insiders to disclose information necessary to prevent fraud on the government."

label promotion directed at his spine surgeon and on which the surgeon relied, but he also fails to allege who made those representations to his surgeon and when the representations were made. Rule 9(b) requires more than the generalized allegations made here.").

In their opposition, relators argued that the corrected third amended complaint satisfied Rule 9(b). At the hearing, however, they disclaimed any intention of pleading an implied false certification claim based on off-label promotion. The court nonetheless addresses the off-label promotion arguments made in their opposition, as this is the only theory on which the court granted leave to amend upon dismissal of the second amended complaint. In their opposition, relators contend they adequately alleged that it was defendants' corporate-wide policy and practice to train their representatives to tell physicians that all stimulators are the same and therefore that their lumbar devices could be safely used on the cervical spine.[100] In particular, they cite paragraphs 131 and 143. Paragraph 131 alleges that Milko "learned from DJO personnel that its sales representatives are instructed to tell physicians that [it is] permissible to use their lumbar device on the cervical spine."[101] Paragraph 143 states that Milko "was also informed by EBI personnel at trade conventions that its sales representatives routinely tell physicians that it is permissible to use their lumbar device on the cervical spine."[102] Neither allegation satisfies Rule 9(b).

Although both paragraphs sufficiently allege the "content" of the purported promotional statements, neither identifies who made the statements. Where fraud has allegedly been perpetrated by a corporation, a plaintiff must allege the names of the employees or agents who purportedly made the statements or omissions that give rise to the claim, or at a minimum identify them by title and/or job responsibility. See, e.g., *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1051 (9th Cir. 2001) (holding that Rule 9(b) was not satisfied, *inter alia*, because plaintiff did not "identify the [defendant's] employees who performed the tests, or provide any dates, times, or places the tests were conducted"); *Arch Ins. Co. v. Allegiant Prof'l Bus. Servs., Inc.*, No. CV 11-1675 CAS (PJWx),

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[100]Opposition at 8.

[101]TAC, ¶ 131.

[102]*Id.*, ¶ 143.

2012 WL 1400302, *3 (C.D. Cal. Apr. 23, 2012) ("The requirement of specificity in a fraud action against a corporation requires the plaintiff to allege the names of the persons who made the allegedly fraudulent representations, their authority to speak, to whom they spoke, what they said or wrote, and when it was said or written"); *Dooms v. Fed. Home Loan Mortgage Corp.*, No. CV F 11-0352 LJO DLB, 2011 WL 1232989, *14 (E.D. Cal. Mar. 31, 2011) ("In a fraud action against a corporation, a plaintiff must 'allege the names of the persons who made the allegedly fraudulent representations, their authority to speak, to whom they spoke, what they said or wrote, and when it was said or written'"); *Flowers v. Wells Fargo Bank, N.A.*, No. C 11–1315 PJH, 2011 WL 2748650, *6 (N.D. Cal. July 13, 2011) (same). The corrected third amended complaint does not do this. It simply states that unidentified "DJO personnel" and "EBI personnel" informed Milko of defendants' purported policy and practice.[103] At a minimum, relators must identify the speakers by their job titles and/or responsibilities. See *Bennett*, 747 F.Supp.2d at 779 ("The relators have not identified any Medtronic employees who engaged in off-label promotion nor specific physicians or hospitals who received the promotions. They have not alleged the 'who' or 'where' of the alleged fraud."). Because they do not, the allegations do not adequately plead off-label promotion, and thus the submission of a false claim or false certification, under Rule 9(b).

The allegations also fail to state with particularity when and/or where the alleged statements were made. Although relators allege that Milko attended the national convention of the American Academy of Orthopedic Surgeons in Chicago in March 2013, and spoke with DJO representatives there, they do not allege that Milko learned about alleged off-label promotion at the convention. All that is alleged in paragraph 131 is that Milko "has *also* learned from DJO personnel that sales representatives are instructed to tell physicians that [it is] permissible to use their lumbar devices on the cervical spine," i.e., that it is permissible to use its devices off-label.[104] This allegation provides no information as to where or when the statements were made, let alone by whom they were made. Similarly, although paragraph 143 alleges that EBI personnel told Milko that the company's sale representatives advise

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[103]TAC, ¶¶ 131, 143.

[104]*Id.*, ¶ 131.

physicians that it is permissible to use its devices on the cervical spine "at trade conventions," the conventions are not identified by name, location or date.[105] For this reason as well, paragraphs 131 and 143 fail adequately to plead off-label promotion such as would support their allegations of an impliedly false certification.

Relators also allege that Milko "became aware over time that DJO and Biomet were distributing their spinal, lumbar only, non-invasive bone growth stimulators off-label for cervical use."[106] He purportedly "heard that cervical patients fitted with SpinaLogic bone growth stimulators by DJO sales personnel were verbally instructed to use the DJO device by folding it up, placing a pillow over it and lying their head on the pillow for 30 minutes"; he allegedly "also heard" that DJO personnel told patients who questioned the off-label use that "it would work even better on the cervical spine since that was a smaller area to heal."[107] As with the previous allegations, however, there is no indication of who made the statements Milko "heard." Nor is there any indication when or where the statements were made. Although a plaintiff can plead a reasonable range of dates under Rule 9(b), relators do not provide even a range of time during which the promotional statements were purportedly made. Compare *Interserve, Inc. v. Fusion Garage PTE. Ltd.*, No. CV-09-5812-RS-PSG, 2011 WL 500497, *3 (N.D. Cal. Feb. 9, 2011) (denying a motion to dismiss where allegations of "purported fraud [were] limited to a narrow window of time"); *United States v. Hempfling*, No. CV 05-00594-OWW-SMS, 2005 WL 2334713, *6 (E.D. Cal. Sept. 23, 2005) ("While Rule 9(b)'s particularity requirement is not as stringently applied where fraud is alleged to have occurred over a longer period of time, Plaintiff's complaint lacks even a range of dates during which [defendant] held his seminars, posted information on his website, and sold his products"). Accordingly, this allegation is also insufficient to plead off-label promotion.[108]

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[105] *Id.*, ¶ 143.

[106] TAC, ¶ 127.

[107] *Id.*

[108] Relators appear to suggest that paragraphs 134-36, 138, 141-44, and 146 support their off-label promotion theory. The court disagrees. These paragraphs do not concern off-label promotion. Indeed,

Finally, paragraph 32 of the corrected third amended complaint also fails under Rule 9(b). It contains no particularized allegations; instead, it states generally that "Defendants' agents and employees . . . are not licensed physicians, but [ ] nevertheless advised patients on dosage . . . and provided ad hoc instructions on how to modify the use of the device in order to use it in this unapproved anatomical location."[109] The paragraph also states that "[d]efendants' agents and employees . . . provided verbal assurances regarding the purported safety and effectiveness of these devices when used in [an] off-label manner."[110] Like the previous allegations, this falls far short of the required particularity demanded by Rule 9(b). Not only are the agents or employees unidentified, but the allegation fails to distinguish between defendants. Rule 9(b) "does not allow a complaint . . . merely [to] lump multiple defendants together but 'require[s] plaintiffs to differentiate their allegations when suing more than one defendant . . . and inform each defendant separately of the allegations surrounding his alleged participation in the fraud.'" *Swartz v. KPMG LLP*, 476 F.3d 756, 764-65 (9th Cir. 2007) (quoting *Haskin v. R.J. Reynolds Tobacco Co.*, 995 F.Supp. 1437, 1439 (M.D. Fla. 1998)); *Moore*, 885 F.2d at 541 (holding that in the context of a fraud suit involving multiple defendants, a plaintiff must, at a minimum, "identif[y] the role of [each] defendant[ ] in the alleged fraudulent scheme"). Moreover, there is no suggestion of when or where the advice and assurances were given. As a result, the allegation does not adequately plead any false certification due to off-label promotion.

Relators assert that defendants place the pleading bar too high; they contend that defendants' motion to dismiss is premised on the absence of "exemplar details relating to claims from each

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as defendants note, this is confirmed by the fact that these paragraphs appear almost verbatim in the second amended complaint, i.e., a complaint that relators asserted did not allege off-label promotion. (Order at 59 n.186 ("As the court has noted multiple times, however, relators explicitly state that they *do not assert that defendants unlawfully marketed their devices*. . . . Indeed, there are no allegations of unlawful marketing in the complaint" (emphasis added)); Opposition to Motion to Dismiss Second Amended Complaint, Docket No. 60 (Mar. 19, 2014) at 26-27.)

[109] TAC, ¶ 32.

[110] *Id.*

government program."[111] Defendants nowhere suggest exemplar detail is required, and the court agrees with relators that it is not. See *Ebeid*, 616 F.3d at 998 ("We do not embrace the district court's categorical approach that would, as a matter of course, require a relator to identify representative examples of false claims to support every allegation, although we recognize that this requirement has been adopted by some of our sister circuits."). Rather, defendants clearly contend that relators have failed to allege facts concerning their purported off-label marketing with the specificity demanded by Rule 9(b). They note, correctly, that the "general sort of fraudulent conduct" relators plead, which "specifies no particular circumstances of any discrete fraudulent statement, is precisely what Rule 9(b) aims to preclude." See *Cafasso*, 637 F.3d at 1057 (affirming the dismissal of an FCA claim based on failure to comply with Rule 9(b)); *Bennett* ,747 F.Supp.2d at 782 ("In the complaint filed in the present case, the relators have not cited 'particular patients, dates, and corresponding medical records' for the alleged upcoding. Nor have the relators alleged with particularity that any physician or hospital submitted a false claim for reimbursement. These allegations do not plead fraud with the particularity required by Rule 9(b)"). The court thus dismisses relators' federal FCA claim premised on false Medicare claims.

b. Whether the Corrected Third Amended Complaint Sufficiently Alleges that Medicare Conditioned Payment on Compliance with the FDA's PMA Supplement Regulation

To allege an FCA implied false certification claim adequately, relators must plead that the claimant failed to comply with a law, rule, or regulation upon which payment of the claim was conditioned. *Ebeid*, 616 F.3d at 998 ("a complaint alleging implied false certification must plead with particularity allegations that provide a reasonable basis to infer[, *inter alia*,] that the defendant explicitly undertook to comply with a law, rule or regulation that is *implicated in submitting a claim for payment*" (emphasis added)). Defendants contend that even had relators adequately pled that they engaged in off-label marketing of their stimulators, they do not – and cannot – plausibly allege that Medicare conditions payment for medical devices on the device manufacturer's compliance with the FDA's PMA supplement

[111]Opposition at 7.

regulation.[112] Again, the court must agree with defendants.

Nowhere in the complaint do relators cite any Medicare statute, regulation, or program requirement that states Medicare conditions payment for medical device claims on a manufacturer's compliance with PMA supplement requirements. Relators dispute this, arguing that they have adequately alleged that defendants "undertook to comply with all applicable laws."[113] The only certifications identified in the complaint (or raised in relator's opposition), however, have nothing to do with FDA PMA supplement regulations. Some of the allegations merely allege that defendants signed Medicare certification statements, which in and of itself says nothing about whether Medicare requires manufacturers to comply with FDA PMA supplement regulations.[114]

Relators appear to contend that 42 C.F.R. § 424.57 is a regulation that requires manufacturers to comply with the FDA's PMA supplement rules.[115] Specifically, they cite § 424.57(c). This regulation requires that a manufacturer applying for billing privileges from Medicare certify that it meets and will continue to meet "[f]ederal regulatory requirements that specify requirements for the provision of [DME] and ensure accessibility for the disabled." See 42 C.F.R. § 424.57(c)(1)(i). There is no case law that addresses directly whether this provision requires that manufacturers of a medical device prescribed or used for an off-label purpose comply with the FDA's requirement that they file a PMA supplement if they engage in off-label promotion of the device. Assuming, without deciding, that § 424.57(c) required defendants to file a PMA supplement if they were engaged in off-label promotion of the stimulators, the court cannot find that violating § 424.57(c) will support the imposition of FCA liability on defendants. The Sixth Circuit addressed this question in *United States ex rel. Williams v. Renal Care Group, Inc.*, 696 F.3d 518, 531-32 (6th Cir. 2012). There, defendant dialysis suppliers argued that their alleged violation of the certification requirements set forth in § 424.57(c) for billing privileges

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[112]Motion at 14.

[113]Opposition at 39.

[114]TAC, ¶¶ 9-10.

[115]See Opposition at 6 (citing TAC ¶¶ 96-110 for proposition that defendants "undertook to comply with all applicable laws"). See also TAC, ¶¶ 96-110 (referring to 42 C.F.R. § 424.57).

applications did not render their claims "materially false," because the certification of compliance was not a condition or prerequisite of payment and thus could not subject them to FCA liability. *Id*. at 532 (quoting *United States ex rel. Gross v. AIDS Research Alliance–Chicago*, 415 F.3d 601, 604 (7th Cir. 2005)). The Sixth Circuit agreed. It stated:

> "The defendants are correct, irrespective of whether they in fact violated the regulations. The [FCA] is not a vehicle to police technical compliance with complex federal regulations. . . . The regulations set forth in[§ 424.57(c)] are conditions of participation, the violation of which do not lead to [FCA] liability. Consequently, the district court erred in granting summary judgment in favor of the United States on this claim, and the defendants' motion for summary judgment as to Count Two is granted." *Id*.

See also *Gross*, 415 F.3d at 604 ("An FCA claim premised upon an alleged false certification of compliance . . . also requires that the certification of compliance be a condition of or prerequisite to government payment"); *United States v. Chubb Inst.*, No. CIVA 06 3562, 2010 WL 1076228, *5 (D.N.J. Mar. 22, 2010) ("Consequently, the overwhelming majority of courts have extended False Claims Act liability to a party's knowingly false certification of compliance with applicable regulations when such regulations are a condition of payment"); *Hansen v. Freedom Mobility, Inc.*, No. 5:08–CV–131, 2009 WL 3784958, *2 (W.D.N.C. Nov. 10, 2009) ("Failure to comply with regulations regarding billing or insurance might result in removal of Medicare billing privileges by the government, see 42 U.S.C. § 424.57(c), but would not establish any tort or negligence liability here"); *United States ex rel. Landers v. Baptist Mem'l Health Care Corp.*, 525 F.Supp.2d 972, 978-79 (W.D. Tenn. 2007) (holding that there was no FCA liability for violations of conditions of participation, which are "the requirements providers must meet to participate in the Medicare program," because CMS forms do not expressly or impliedly condition payment on compliance with participation conditions); *United States ex rel. Cooper v. Gentiva Health Servs., Inc.*, No. CV 01-0508, 2003 WL 22495607, *9 (W.D. Pa. Nov. 4, 2003) ("In sum, Section 424.57 makes abundantly clear that the proper redress for violations of the standards established therein is not the denial of payment, but the revocation of the supplier's billing privileges, with or without the assistance of beneficiary complaint procedures. Thus, the Plaintiff may not properly proceed under the implied certification theory for alleged violations of Section 424.57").

Williams and the other authority cited is persuasive. Section 424.57 does not concern reimbursement, and contains its own internal sanction – i.e., loss of billing privileges. See 42 C.F.R. § 424.57(e) ("CMS will revoke a supplier's billing privileges if it is found not to meet the [applicable standards]"); see also *Williams*, 696 F.3d at 531-32 (noting same). Accordingly, to the extent premised on the notion that § 424.57(c) requires that manufacturers promoting stimulators for off-label use comply with the PMA supplement process in order accurately certify compliance with Medicare, realtors' FCA Medicare claim must be dismissed.[116]

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[116]At the hearing, relators argued that their implied false certification claim was based on defendants' failure to comply with Medicare's overarching "reasonable and necessary" requirement. At the same time, they disclaimed any claim based on off-label promotion, twice arguing that this was "not their theory." Rather, relators assert that defendants' submission of claims for off-label use of their devices was unlawful because the devices are not medically accepted for such uses, i.e. reasonable and necessary. The court previously found this argument unavailing because it concluded that off-label use of defendants' devices is not categorically prohibited. (See Order at 46-50.)

As the court explained in the order dismissing the second amended complaint, HHS "may make [Medicare] coverage determinations [for certain types of devices] via up-front rules" and has "discretion [to decide] whether to make [broad] determinations [as to whether a particular device is reimbursable] . . . or [whether to have Medicare contractors make that decision based on a] case-by-case adjudication." *International Rehabilitative Sciences*, 688 F.3d at 1001. When HHS engages in rulemaking regarding the scope of coverage for certain devices, it issues NCDs, which are "a determination . . . of whether a particular item or service is covered nationally under Medicare." 42 C.F.R. § 405.1060(a)(1). NCDs outline the conditions under which a device or service will be covered (or not covered), and are binding on all contractors. See 42 C.F.R. § 205.1060(a); *Almy*, 679 F.3d 299; *Erringer v. Thompson*, 189 F.Supp.2d 984, 987 (D. Ariz. 2001) ("An NCD is binding on all carrier[ ]s, fiscal intermediaries, and ALJs"); see also *Fratellone v. Sebelius*, No. 08 Civ. 3100(RMB)(RLE), 2009 WL 2971751, *5 (S.D.N.Y. Sept. 16, 2009) ("NCDs are binding on fiscal intermediaries, carriers, QICs, ALJs, and the MAC"). They reflect CMS's determination as to whether a particular device or service is reasonable and necessary; this includes a determination concerning the device's or service's safety and efficacy.

In the prior order, the court noted that NCD 150.2 covers stimulators, and states that "[t]he noninvasive stimulator device is covered only for the following indications: . . . as an adjunct to spinal fusion surgery." (*Id*. at 47.) The court observed that LCDs for stimulators provide identical coverage; it stated that nothing in NCD 150.2 or LCDs limits coverage for stimulators to those supplied for on-label use, nor otherwise differentiates between stimulators used on different areas of the spine. (*Id*.) Consistent with this reading of NCD 150.2 and the LCDs covering stimulators, CMS 847 does not ask where on the spine the device for which reimbursement is sought was to be used or for what use(s) the FDA has approved the device. Similarly, the HCPCS code for stimulators – E0748 – is the same whether the device is used on the lumbar or cervical spine. Further supporting the fact that the broad language of NCD 150.2 covers *all* noninvasive stimulators used as an adjunct to spinal fusion surgery (including stimulators approved only for use on a part of the spine different than that for which they were prescribed) is the fact that numerous NCDs and LCDs explicitly limit reimbursable use of particular devices to on-label uses, see NCD 290.9, § B.1-B.3; NCD 50.3, § B.1; NCD 20.32, § B; LCD

Relators also assert that the Medicare Benefit Policy Manual states that Medicare may cover "[d]evices approved by the FDA through the [PMA] process."[117] Because the Medicare Manual describes PMA approval as a "process," relators contend that PMA approval is not a one-time event, and that compliance with PMA supplement regulations is also required as part of the overall "PMA process." The court agrees with defendants that this argument lacks merit.[118] The court, in fact, has already found this argument unavailing. In its prior order dismissing the second amended complaint, the court explained that the Medicare Benefit Policy Manual clearly "states that 'devices' approved through the PMA process are eligible for coverage, not that 'the use of a device' that has been approved by the FDA is eligible for coverage."[119] Indeed, as the court discussed in its prior order, CMS' December 17, 2003 coverage decision memorandum reconsidering coverage of the use of electrostimulation devices for the treatment of chronic wounds supports the conclusion that the "device approved by the FDA" language in the Medicare Benefit Policy Manual means that if a device has been approved for any use by the FDA, CMS can conclude that a particular use is reimbursable even if that use is off-label. In the memorandum, CMS stated:

> "The FDA [ ] considers the use of [electrostimulation] devices for the treatment (healing) of wounds to be significantly different than the use of these devices for the indications currently covered under a 510(k) clearance. When used to treat wounds,

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L30312; provide coverage for both on-label and off-label uses under certain specified conditions, see LCD L35084; LCD L33500; or explicitly exclude coverage for off-label uses, see LCD L32220; LCD L32028. These NCDs and LCDs demonstrate that CMS understands how to limit coverage of devices to on-label uses when it determines that doing so is reasonable and necessary. Where an NCD make no such distinction, as is the case here, it must be interpreted to cover both on- and off-label uses of the devices in question. Additionally, the court did not grant relators leave to amend this aspect of their earlier implied false certification claim. Relators' opposition is thus a motion for reconsideration which the court denies.

Finally, even were there merit to relators' argument, as discussed *infra*, their allegations of scienter fail in light of the existence of the NCDs and LCDs cited above. For all of these reasons, the court finds relators' reasonable and necessary argument is unpersuasive.

[117]Opposition at 38 (citing Medicare Benefit Policy Manual, Ch. 14, § 10).

[118]Reply at 8.

[119]Order at 40.

> these devices are considered by the FDA to be Class III devices, which requires the manufacturer to go through the Premarket Approval (PMA) process. Therefore, manufacturers would have to submit valid scientific evidence to show that their products provide reasonable assurance of safety and effectiveness for the treatment of wounds before the FDA would approve a PMA application. As of this time, the law prohibits manufacturers from marketing the use of electromagnetic devices for wound healing. Lack of approval for this particular indication, however, does not preclude physicians and other health care providers from providing this therapy for an unapproved use. *In addition, lack of FDA approval or clearance for a specific non-labeled indication, when there are other labeled indications, is not an automatic disqualification for Medicare coverage*. In addition, CMS assesses relevant health outcomes, above and beyond the safety and effectiveness regulatory mandate of the FDA. Although a device must receive FDA approval or clearance for at least one indication to be eligible for Medicare coverage . . . , FDA approval/clearance alone does not entitle that device to coverage. . . . CMS has the authority to conduct a separate assessment of a device's appropriateness for Medicare coverage, including whether it is reasonable and necessary specifically for its intended use for Medicare beneficiaries"[120]

This passage makes it clear that if the FDA has approved a device for at least one purpose, an off-label use can be reimbursed by Medicare. Cf. Medicare Benefit Policy Manual, § 50.4.2 ("An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. In the case of drugs used in an anti-cancer chemotherapeutic regimen, unlabeled uses are covered for a medically accepted indication as defined in § 50.5"). It therefore

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[120]Defendants' Prior Supp. RJN, Exh. 2 at 358-359 (at 6-7) (emphasis added).

supports the court's conclusion that CMS' use of the phrase "device approved by the FDA" in the Medicare Benefit Policy Manual does not mean "a use of a device that has been approved by the FDA," and that there is no categorical ban on the coverage of devices for off-label uses.

The explicit terms of certain of the NCDs and LCDs also support the court's conclusion that the Medicare Manual's use of the term *devices* approved by the FDA does not mean the *particular use of a device* approved by the FDA. Some NCDs and LCDs, for example, specifically limit the reimburseable use of particular devices to those for which they have been approved by the FDA. See NCD 20.9, § B.1-B.3 (stating that ventricular assist devices ("VADs") "used for support of blood circulation post-cardiotomy are covered only if they have received approval from the [FDA] for that purpose, and are used according to the FDA-approved labeling instructions. . . . VADs used for bridge-to-transplant are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to the FDA-approved labeling instructions. . . . VADs used for destination therapy are covered only if they have received approval from the FDA for that purpose");[121] NCD 50.3 § B.1 (stating that cochlear implants for the treatment of certain types of hearing loss are only covered if "used in accordance with [FDA]-approved labeling");[122] LCD L30312 (providing coverage for an ablative device only if it is "FDA-approved for the indications used");[123] see also NCD 20.32, § B (stating that the Transcatheter Aortic Valve Replacement ("TAVR") is covered when used "for the treatment of sympomatic aortic valve stenosis when furnished according to a [FDA]-approved indication," and only if, *inter alia*, "[t]he procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval (PMA) for that system's FDA approved indication").[124]

Some LCDs specify that both on-label use and off-label use of devices is covered when supported by peer-reviewed literature. See, e.g., LCD L35084 (covering non-coronary vascular

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[121] *Id.*, Exh. 1 at 39 (Medicare National Coverage Determinations Manual).

[122] *Id.* at 83.

[123] *Id.*, Exh. 4 at 388 (LCD L30312).

[124] *Id.*, Exh. 1 at 65 (Medicare National Coverage Determinations Manual).

stents "only when an FDA-approved stent is" either (1) "[u]sed for the FDA-approved indications" or (2) for certain other enumerated indications "supported by the peer medical literature");[125] LCD L33500 (stating that the contractor would "continue to limit payment for Vertebral Augmentation to those diagnostic indications which are either part of the FDA labeling or which are supported by appropriate peer-reviewed literature").[126] Finally, other LCDs specifically exclude coverage for off-label uses. See LCD L32220 (excluding coverage for "any off-label uses" of FDA-cleared transcranial magnetic stimulation devices);[127] LCD L32028 (stating that the contractor "considers repetitive transcranial magnetic stimulation (rTMS) not medically necessary regardless if used for its FDA-approved indication or for any off-label uses").[128]

As the court previously concluded, none of these distinctions would be required if coverage for off-label use of devices were categorically prohibited.[129] These exemplar NCDs and LCDs provide further support for the conclusion that the Medicare Manual's use of the term "devices approved by the FDA" does not mean "use of a device approved by the FDA." Consequently, the court concludes that relators misinterpret the section of the Medicare Manual on which they rely, and to the extent their claim is based on that interpretation, it is not viable. See *Nowak*, 806 F.Supp.2d at 347-48 ("[T]o the extent that Nowak's claim alleges that the claims for off-label use are 'categorically' false because the device is unapproved for that use (and thus 'misbranded' or 'adulterated' or 'investigational'), she fails adequately to state a claim for relief in accordance with Rule 12(b)(6)"); see also *Bennett*, 747 F.Supp.2d at 752 ("Medicare reimbursement[ ] for off-label uses of medical devices [is] not addressed within the Medicare Act itself").

In sum, relators have failed to identify any Medicare statute, regulation, or program requirement that conditions payment for medical device claims on the manufacturer's compliance with PMA

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[125] *Id.*, Exh. 5 at 403 (LCD L32641).

[126] *Id.*, Exh. 6 at 417 (LCD L33500).

[127] *Id.*, Exh. 3 at 378 (LCD L32220).

[128] *Id.*, Exh. 7 at 430 (LCD L32038).

[129] Order at 43.

supplement requirements. They therefore fail plausibly to allege that Medicare conditions payment for medical devices on the device manufacturer's compliance with the FDA's PMA supplement regulation. Thus, even had they adequately alleged that defendants engage in off-label promotion of their stimulators, the court would dismiss the Medicare FCA claim for this reason.

c. Whether the Corrected Third Amended Complaint Adequately Alleges That Defendants Acted with Scienter

The deficiencies the court has noted in relators' pleading of falsity also render inadequate their allegations of scienter. The court previously found that relators failed to allege scienter sufficiently because none of the statutes, regulations, NCDs, LCDs, or claim forms referenced in the second amended complaint or discovered independently by the court indicated that defendants were required to disclose the fact that they sought reimbursement for devices prescribed for off-label use. Consequently, none put defendants on notice that they needed to do so.[130] Relators have not cured the deficiencies in the pleading of scienter noted in the prior order, and offer only a minimal response to defendants' argument on this point in their opposition.

Relators' only argument is that intent and knowledge can be alleged generally in an FCA case.[131] It is true that Rule 9(b) does not require particularized allegations of knowledge or intent. Relators' allegations, however, fall short of plausibly pleading scienter under Rule 8, *Twombly*, and *Iqbal*. They allege that defendants "knew that they were falsely and/or fraudulently claiming reimbursements" and "knew [their devices] were being unlawfully sold for unapproved off-label cervical use."[132] None of the facts relators plead, however, support their conclusory allegation that defendants knowingly submitted false claims.

As in the second amended complaint, relators do not cite any Medicare statute, regulation, NCD, LCD, or claim form that indicates manufacturers like defendants must disclose the fact that they seek reimbursement for devices prescribed for off-label use, or that they must file a PMA supplement before

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[130]Order at 60-61.

[131]Opposition at 20.

[132]TAC, ¶ 150

seeking reimbursement. No facts alleged by relators give rise to a reasonable inference that defendants were on notice they were filing false claims. In the absence of any factual allegations supporting relators' assertion that defendants acted with the requisite scienter, their allegations that defendants "knew that they were falsely and/or fraudulently claiming reimbursement" and "knew [their devices] were being unlawfully sold for unapproved off-label cervical use" are too conclusory to plead a plausible claim for relief, even under the relaxed standard of Rule 8(a). Accordingly, the court again concludes that relators have failed adequately to allege scienter, and dismisses their Medicare FCA claim on this basis as well.

d. Whether the Corrected Third Amended Complaint Adequately Alleges that Defendants Made False Certifications

In addition to the basis for dismissal already discussed, the court also concludes that relators have failed to plead with particularity when any of defendants' purported certifications of compliance occurred.[133] This is because relators have failed to plead facts satisfying *Ebeid.* To plead an implied false certification claim adequately under *Ebeid*, relators must allege that "(1) the defendant explicitly undertook to comply with a law, rule or regulation that is implicated in submitting a claim for payment and that (2) claims were submitted (3) even though the defendant was not in compliance with that law, rule or regulation." *Ebeid*, 616 F.3d at 998. As was the case in their second amended complaint, relators have not sufficiently alleged the first of the three elements identified forth in *Ebeid.* Relators plead that every three years defendants signed a Medicare Enrollment Application, pursuant to 42 C.F.R. § 424.57, that certified compliance with all applicable rules and regulations, and stated that defendants "understood that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions."[134] Relators, however, have not alleged with particularity when the certifications took place. They plead only that "[i]n order

[133]Order at 57.

[134]TAC, ¶¶ 99-100.

to obtain and retain billing privileges as a Medicare provider, DJO [and Biomet] ha[ve] certified every three years covering all periods of time relevant to the allegations in this complaint, including the period of September 18, 2001 to the present, that [they] meet[ ] and will continue to meet all applicable federal and state licensure and regulatory requirements."[135] An identical allegation was included in the second amended complaint.[136] As the court determined with respect to the earlier allegations, pleading that defendants made the certifications on "unspecified dates in unspecified years does not satisfy the heightened pleading requirement of Rule 9(b)."[137] Relators do not appear to address this point in their opposition. For the same reason it earlier found this allegation insufficient, the court does so again. The court therefore dismisses relators' Medicare FCA claim on this basis as well.

e. Conclusion Regarding Relators' Ability to State a FCA Claim Based on Defendants' Submission of Claims to Medicare

Because relators have failed (i) to plead with particularity facts showing that defendants engaged in off-label promotion of their stimulators; (ii) to allege facts demonstrating that defendants were required to file a FDA PMA supplement as a prerequisite to obtaining reimbursement for off-label use of their stimulators;[138] (iii) to allege scienter plausibly; and (iv) to state with particularity when

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[135]*Id*.

[136]SAC, ¶¶ 5-6.

[137]Order at 56.

[138]For the same reason, relators have failed to allege adequately that defendants' failure to disclose that the stimulators were prescribed for off-label use was material. "To establish materiality . . . the question is merely whether the false certification – or assertion, or statement – was relevant to the government's decision to confer a benefit." *Ebeid*, 616 F.3d at 997 (citing *Hendow*, 461 F.3d at 1173). As the court previously noted, the fact that Medicare does not limit coverage of stimulators to on-label uses indicates the failure to disclose that a stimulator was going to be used for an off-label use was not material to the government's reimbursement decision. (Order at 58 n. 182.) This conclusion is reinforced by the fact that neither CMS Form 1500 nor CMS 847 includes a question regarding the use to which the stimulator will be put or the scope of FDA approval of the stimulator. See *United States ex rel. Hess v. Sanofi-Synthelabo, Inc.*, No. 4;05CV570MLM, 2006 WL 1064127, *7 (E.D. Mo. Apr. 21, 2006) ("According to Plaintiff's Complaint, ¶ 13, although 'the Medicare claim form has a line for indicating the patient's diagnosis,' it 'does not require a doctor to indicate what stage cancer the patient has.' As such, the stage of a patient's cancer is not material to a doctor's seeking reimbursement for his or her prescribing Eloxatin for treatment of cancer. The

defendants made the allegedly false certifications, the court grants defendants' motion to dismiss relators' federal Medicare FCA claim.

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stage of a patient's cancer, therefore, was not material to [the government] in making a decision to reimburse doctors for their prescription of Eloxatin").

3. FCA Liability Premised on Submission of False Claims to Medicaid and other Federal Reimbursement Programs

a. Whether the Corrected Third Amended Complaint Adequately Alleges that Defendants Submitted False Claims for Medicaid Reimbursement

The federal government reimburses a portion of the cost of DME under the Medicaid program, Federal Employees Health Benefit Program, Federal Worker's Compensation Programs, CHAMPVA, and Tricare. Relators contend that defendants submitted false claims to these programs as well.[139] Defendants argue that relators have not adequately alleged an FCA claim based on their submission of claims to these programs because the complaint contains no allegations indicating that the programs reimburse defendants' devices any differently than Medicare.[140]

As noted, relators' FCA claim must satisfy the heightened pleading requirements of Rule 9(b). Relators must therefore "set forth what is false or misleading about [the] statement and why it is false." *Ebeid*, 616 F.3d at 998. Relators' complaint contains a cursory review of the Medicaid laws of forty-four states and the District of Columbia. Defendants contend these allegations are insufficient, because they (i) contain no reference medical devices or state that medical devices are covered only when prescribed for FDA-approved uses; and (ii) do not indicate that any state considered defendants' devices experimental or investigational.[141] Defendants concede that some states cover only "medically necessary" services and devices, and/or exclude "experimental" services or devices; they contend, however, that there are no facts alleged that would support a finding that these programs exclude physician-prescribed cervical use of the SpinalPak or SpinaLogic.[142] The court agrees. Relators identify only six states that allegedly exclude payment for DME that has not received FDA PMA approval for its intended use. The court addresses each in turn.

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[139]TAC, ¶ 117.

[140]Motion at 18.

[141]*Id*.

[142]*Id*.

Relators allege that Florida limits Medicaid coverage to medically necessary DME, which is defined as "not experimental or investigational." "Experimental or investigational" in turn is defined as "used for a purpose that is not approved by the FDA."[143] Although this allegation can be read to cover defendants' devices, they contend the allegation fails under Rule 9(b) because relators do not plead: (i) the time period during which this limitation has been in effect, (ii) that either defendant submitted claims for its device to Florida's Medicaid program, (iii) that either defendant made false statements to Florida's Medicaid program about FDA approval of its device, or (iv) that either defendant acted with the requisite scienter.[144] The court must agree with defendants. Relators allege no facts indicating that either defendant submitted a claim to the Florida Medicaid program, and no facts indicating that the limitation on coverage cited in the complaint was in effect when the claim was submitted. Any claim based on the submission of a false claim to Florida's Medicaid program is therefore deficient under Rule 9(b).[145]

The same is true of relators' allegations concerning the Hawaii, Michigan, Nebraska, and Nevada Medicaid programs; although relators allege that these states require that intended uses be FDA approved, relators do not allege that either defendant submitted a claim or otherwise made false statements to the Medicaid programs in these states.[146] Consequently, they have not satisfied Rule 9(b).

Relators contend that Minnesota's Medicaid Manual dated April 8, 2014 states that bone growth stimulators "should only be used in a way that is consistent with the FDA approved package insert," and

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[143]TAC, ¶ 121.

[144]*Id.* at 19.

[145]The court notes that relators allege that the District of Columbia Medicaid program also prohibits "experimental procedures." (*Id.*) Relators do not allege that "experimental procedures" are linked to compliance with FDA rules, however. Even if they did, these allegations fail for the same reasons as the allegations concerning the Florida Medicaid program, i.e., relators allege no facts indicating that either defendant submitted a claim to the District of Columbia Medicaid program, nor any facts indicating that the limitation on coverage cited in the complaint was in effect when the claim was submitted.

[146]TAC, ¶ 121.

that the device must be "requested for an FDA approved indication."[147] Relators allege that defendants submitted claims in 2010 and 2012, however, two to four years before the effective date of the Medicaid Manual they reference.[148] They do not allege that this regulation was in effect at the time the claims were submitted. They therefore fail to plead that Minnesota required FDA approval of the intended use of the device at the time claims were submitted, and fail to satisfy Rule 9(b) as a result. Moreover, as noted in the court's prior order, relators do not allege that defendants' claims to the Minnesota Medicaid program failed to disclose that their stimulators had been prescribed for off-label use.[149] This deficiency too requires dismissal.

In sum, the court concludes that relators have failed to allege with particularity that defendants submitted any claim that was inconsistent with any state's Medicaid program requirements. The court therefore dismisses the state Medicaid aspects of the FCA claim.

b. Whether the Corrected Third Amended Complaint Adequately Alleges Submission of False Claims to Other Government Agencies

Defendants argue that the court dismissed relators' FCA claim in the second amended complaint to the extent based on the submission of claims to other federal government programs for at least four reasons: (i) relators did not allege the reimbursement rules for these programs, and thus failed to plead with particularity that they did not cover off-label uses of the stimulators;[150] (ii) they failed to plead that defendants made certifications to these programs or what the content of such certifications was;[151] (iii) they did not plausibly plead scienter;[152] and (iv) the second amended complaint did not allege with particularity any representative sample of false claims submitted to these programs or reliable indicia

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[147] *Id*.

[148] *Id.*, ¶¶ 139, 146.

[149] See *id.* See also Order at 62.

[150] Order at 59.

[151] *Id*. at 60 n. 187.

[152] *Id*. at 60. Scienter is addressed separately in subsection (c) of the order.

that supported a strong inference that false claims were submitted.[153] Defendants maintain that relators added no new allegations to cure any of these deficiencies, despite the fact that the court offered suggestions as to how they might do so.[154] The court agrees.

Relators have not included any allegations concerning the rules governing reimbursement under any of these programs in the third amended complaint; this renders allegations that defendants submitted false claims conclusory and implausible. There are, likewise, no allegations that defendants ever made certifications to these programs; no representative examples are pled, nor any reliable indicia that supporting a strong inference that false claims were submitted. Relators not only failed to add allegations on these subjects in their corrected third amended complaint, but failed to address the deficiencies noted by defendants in their motion to dismiss in their opposition. The court must therefore dismiss these claims yet again.

c. Scienter

Even had relators adequately alleged defendants' submission of false claims or certifications to these programs, they have not cured the deficiencies the court earlier found in their allegations of scienter. As discussed in some detail in addressing relators' Medicare allegations, they do not plead facts that support their conclusory assertion that defendants acted with scienter. The allegations are thus insufficient under Rule 8(a). Consequently, relators' FCA claim premised on submission of false claims to federal programs other than Medicare must be dismissed.

C. Whether the Court Should Exercise Supplemental Jurisdiction over Relators' State Law Claims

Relators' federal FCA claim provides the sole basis for federal subject matter jurisdiction in this case. Because relators have not stated a viable federal claim, the court declines to exercise jurisdiction over their state law claims at this time. See *Wade v. Regional Credit Association*, 87 F.3d 1098, 1101 (9th Cir. 1996) ("Where a district court dismisses a federal claim, leaving only state claims for resolution, it should decline jurisdiction over the state claims and dismiss them without

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[153] *Id.* at 62-66.

[154] Motion at 23.

prejudice"); *Harrell v. 20th Century Insurance Co.*, 934 F.2d 203, 205 (9th Cir. 1991) ("[I]t is generally preferable for a district court to remand remaining pendent claims to state court"); *Anderson v. Countrywide Financial*, No. 2:08-cv-01220-GEB-GGH, 2009 WL 3368444, *6 (E.D. Cal. Oct. 16, 2009) ("Since state courts have the primary responsibility to develop and apply state law, and the [*United Mine Workers v.*] *Gibbs* values do not favor continued exercise of supplemental jurisdiction over Plaintiff's state claims, Plaintiff's state claims are dismissed under 28 U.S.C. § 1367(c)(3)"); 28 U.S.C. § 1367(c)(3) ("The district courts may decline to exercise supplemental jurisdiction over a [state-law] claim [if] . . . the district court has dismissed all claims over which it has original jurisdiction"). See also *United Mine Workers of America v. Gibbs*, 383 U.S. 715, 726 (1966) ("Needless decisions of state law should be avoided both as a matter of comity and to promote justice between the parties, by procuring for them a surer-footed reading of applicable law").

D. Whether the Court Should Grant Relators Leave to Amend

Defendants previously asked that the court dismiss relators' federal claim with prejudice, and reiterate that request in their motion.[155] The court's earlier grant of leave to amend was narrow, and its order offered specific suggestions as to how relators could cure deficiencies in the complaint. Much of relators' opposition reargues theories that the court previously concluded could not support an FCA claim and that are beyond the scope of the leave to amend granted. Although they added new allegations, relators failed to cure the deficiencies the court noted in its order dismissing the second amended complaint.

Relators have now had four opportunities to plead a viable FCA claim against defendants; although the court has reviewed the allegations only twice, it concludes, based on the allegations in the corrected third amended complaint, the arguments asserted in their opposition, and the fact that they disclaim any reliance on defendants' off-label promotion of the devices, that relators will not be able to amend to state a viable federal FCA claim based on the submission of claims to Medicare. Compare *Orion Tire Corp. v. Goodyear Tire & Rubber Co.*, 268 F.3d 1133, 1137 (9th Cir. 2001) ("Where counsel

[155]Motion at 25.

is able to posit possible amendments that would be consistent with the operative complaint and could also possibly state a claim for relief, the complaint should not be dismissed on its face with prejudice "). Specifically, relators do not state that they can add additional particularized allegations concerning defendants' alleged off-label promotion, despite having been advised that particularity was required for its implied false certification claim,[156] and despite having had well over a year to plead their case. Nor do relators suggest that they can plead additional allegations that would render their assertion that defendants knowingly submitted false claims plausible. Finally, relators do not assert that they can make particularized allegations concerning defendants' certifications of compliance. Given the number of deficiencies in relators' federal FCA Medicare claim, and the number of opportunities they have had to plead it, the court concludes that relators will not be able to state a viable claim if given leave to amend.

Defendants' FCA claim based on submissions to state Medicaid pleads no particularized allegations that defendants ever submitted any false claims. Relators' response to defendants' argument in this regard is that it rests on a semantic quibble that most state Medicaid provisions lack the term "device."[157] Defendants' argument concerning particularity does not rest on whether the Medicaid provisions include the term "device," however. The only other argument relators advance is that defendants' challenges are "ludicrous and merits no response."[158] This suggests they can offer no substantive response to defendants' critique of the allegations. Finally, as respects relators' contention that defendants submitted false claims to Federal Employees Health Benefit Program, Federal Worker's Compensation Programs, CHAMPVA, and Tricare, the corrected third amended complaint is identical to the second amended complaint. They do not, moreover, address defendants' arguments concerning these allegations in their opposition. Their failure to defend the adequacy of their allegations concerning the submission of false claims to state Medicaid programs, the Federal Employees Health Benefit

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[156]Order at 56 (noting that relators had not alleged it made certifications with the particularity demanded by Rule 9(b)).

[157]Opposition at 35.

[158]*Id.*

Program, the Federal Worker's Compensation Programs, CHAMPVA, and Tricare causes the court to conclude that granting leave to amend would be futile.

For these reasons, the court dismisses all aspects of relators' federal FCA claim with prejudice. See *Kendall v. Visa U.S.A., Inc.*, 518 F.3d 1042, 1051 (9th Cir. 2008) ("Dismissal without leave to amend is proper if it is clear that the complaint could not be saved by amendment"); *California ex rel. California Department of Toxic Substances Control v. Neville Chemical Co.*, 358 F.3d 661, 673 (9th Cir. 2004) ("[D]enial of leave to amend is appropriate if the amendment would be futile," citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

III. CONCLUSION

For the reasons stated, the court grants defendants' motion to dismiss the corrected third amended complaint. Relators' federal FCA claim is dismissed in its entirety with prejudice. The court declines to exercise supplemental jurisdiction over relators' state law claims, and dismisses them without prejudice to refiling in state court.

DATED: May 8, 2015

MARGARET M. MORROW
UNITED STATES DISTRICT JUDGE